THOMAS L. GARTHWAITE, M.D.
Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES
DEPARTMENT OF HEALTH SERVICES
313 N. Figueroa, Los Angeles, CA 90012
(213) 240-8101

March 18, 2004

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, CA 90012

Dear Supervisors:

APPROVAL OF THE CALENDAR YEAR 2004 NATIONAL HANSEN'S DISEASE PROGRAM CONTRACT WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR OUTPATIENT HANSEN'S DISEASE MEDICAL SERVICES (First District) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of Health Services, or his designee, to sign the Calendar Year 2004 National Hansen's Disease Program Contract, No. HHSH258200430004C, substantially similar to (Exhibit I), with the Department of Health and Human Services for outpatient Hansen's disease medical services in the amount of $336,523 for the period effective date of full execution by federal government through December 31, 2004, with an option for two one-year extensions through December 31, 2006, subject to the availability of funds.

2. Delegate authority to the Director of Health Services, or his designee, to sign amendments to the Calendar Year 2004 National Hansen's Disease Program Contract to extend the term through December 31, 2006, with substantially similar terms as the Calendar Year 2004 National Hansen's Disease Program Contract, No. HHSH258200430004C, with the Department of Health and Human Services for outpatient Hansen's disease medical services, in an amount not to exceed $673,046 for these amendments, and following review and approval by County Counsel, and notification to the Board offices.

PURPOSE OF THE RECOMMENDED ACTIONS/JUSTIFICATION:

Board approval of the Calendar Year 2004 National Hansen's Disease Program will enable the Department of Health Services (Department or DHS) to continue the provision of outpatient Hansen's disease medical services at LAC+USC Medical Center for individuals in Los Angeles County Catchment Area.

The program is to provide outpatient health care services and support Hansen's Disease (HD) outreach in areas with HD patient concentration and to enable this patient population to access these services. The central goal is to prevent disability through early diagnosis and treatment of HD.

FISCAL IMPACT/FINANCING:

The total annual operating cost for outpatient Hansen's medical services is $611,157, which is funded by $336,523 in DHHS' National Hansen's Disease Program, funds; $46,515 in estimated Medi-Cal revenue; and $228,119 in net County costs. Funding for this program is included in the Fiscal Year 2003-04 Adopted Budget and will be requested as a continuing appropriation in subsequent years.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

Since 1981, the Board has accepted Awards with the DHHS for the National Hansen's Disease Program for the provision of outpatient Hansen's disease medical services at LAC+USC Medical Center.

In December 2003, the Department successfully competed for funding from the DHHS National Hansen's Disease Program for the continued provision of outpatient Hansen's medical services at LAC+USC Medical Center.

On January 8, 2004, the Department of Health Services received the Calendar Year 2004 National Hansen's Disease Program Contract in the amount of $336,523, for the period effective date of full execution by federal government through December 31, 2004, with an option of two one-year extensions through December 31, 2006, subject to the availability of funding.

LAC+USC Medical Center is designated as a Regional Hansen's Disease Center for the Los Angeles Catchment Area. In addition to Los Angeles County, the Catchment Area includes Orange, Ventura, Tulare, Santa Barbara, San Luis Obispo, Kern, and San Bernardino counties.

The recommended Contract will enable the continuation of outpatient treatment for individuals with HD, case management and follow-up of HD patients, screening of the HD patient's close contacts, and the provision of information and in-service education about HD to healthcare providers. LAC+USC Medical Center provides these services to approximately 532 patients annually.

County Counsel has reviewed and approved the Contract (Exhibit I) as to form.

Attachment A provides additional information.

CONTRACT PROCESS:

Not applicable. Advertisement on the Los Angeles County Online Web Site as a contracting opportunity for the National Hansen's Disease Programs is not appropriate as outpatient Hansen's disease medical services are provided directly by the DHS at LAC+USC Medical Center.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of the recommended actions will ensure the continued availability of vital outpatient Hansen's medical center services in Los Angeles County to prevent disability through early diagnosis and treatment of Hansen's disease.

When approved, this Department requires four signed copies of the Board's action.

Respectively submitted,

Thoms L. Garthwaite, M.D.
Director and Chief Medical Officer

TLG:mc

Attachments (2)

c: Chief Administrative Officer
County Counsel
Executive Officer, Board of Supervisors

BLHansen's 2004.wpd
02/19/04

ATTACHMENT A

SUMMARY OF AGREEMENT

1. TYPE OF SERVICES:

   Provision of outpatient Hansen's medical services and outreach to areas and providers that treat patients with Hansen's disease.

2. AGENCY ADDRESS AND CONTACT PERSON:

   Department of Health and Human Services
   National Hansen's Disease Programs
   1770 Physicians Park Drive
   Baton Rouge, Louisiana 70816-3222
   Attention: Suzanne Shumate, Contracting Officer
   Telephone: (225) 756-3787

3. TERM:

   Date of full execution by federal government through December 31, 2004, with an option of two one-year extensions through December 31, 2006, subject to the availability of funds.

4. GEOGRAPHIC AREA TO BE SERVED:

   First District.

5. FINANCIAL INFORMATION:

   The total operating cost for outpatient Hansen's medical services is $611,157, which is funded by $336,523 in DHHS' National Hansen's Disease Program funds; $46,515 in estimated Medi-Cal revenue; and $228,119 in net County costs.

6. ACCOUNTABLE FOR MONITORING AND EVALUATION:

   Pete Delgado, Chief Executive Officer, LAC+USC Healthcare Network

7. APPROVALS:

   LAC+USC Healtcare Network: Dave Runke, Chief Finance Officer

   Contract and Grants Division: Irene Riley, Chief

   County Counsel (as to form): Kelly Auerbach Hassel, Deputy County Counsel

EXHIBIT I

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CRF 350)	RATING	PAGE OF PAGES 1 16

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
HHSH258200430004C	See Block 20C	04-258-NHDP-001

5. ISSUED BY	CODE NHDP	6. ADMINISTERED BY (If other than Item 5)	CODE NHDP
National Hansen's Disease Program Contracts and Procurement 1770 Physicians Park Drive Baton Rouge LA 70816		National Hansen's Disease Program Contracts and Procurement 1770 Physicians Park Drive Baton Rouge LA 70816	

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)	8. DELIVERY ☐ FOB ORIGIN ☒ OTHER (See below)
LOS ANGELES COUNTY USC MEDICAL CENTER 1200 N STATE STREET LOS ANGELES CA 90033	9. DISCOUNT FOR PROMPT PAYMENT Net 30
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ▶ ITEM See G3
CODE 956000927A	FACILITY CODE

11. SHIP TO/MARK FOR	CODE See F2	12. PAYMENT WILL BE MADE BY	CODE NHDP/FMO
		National Hansen's Disease Program Financial Management Office 1770 Physicians Park Drive Baton Rouge LA 70816	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 USC 2304 (c) ( ) ☒ 41 USC 253 (c) (2)	See Schedule

15A. ITEM	15B. SUPPLIES/SERVICES	15C. QTY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT ▶				$336,523.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	10
X	B	SUPPLIES OR SERVICES AND PRICE/COST	2			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	4	X	J	LIST OF ATTACHMENTS	16
X	D	PACKAGING AND MARKING	5			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	5		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	5				
X	G	CONTRACT ADMINISTRATION DATA	7		L	INSTR., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	8		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 5 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)	18. ☐ AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number 04-258-NHDP-001 including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.
19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER Steven L. Zangwill
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)	19C. DATE SIGNED
20B. UNITED STATES OF AMERICA BY _____ (Signature of the Contracting Officer)	20C. DATE SIGNED

NSN 7540-01-152-8069
PREVIOUS EDITION IS UNUSABLE

STANDARD FORM 26 (Rev. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

LOS ANGELES COUNTY USC MEDICAL CENTER

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 956000927 DUNS Number: 056454895 FOB: Destination				
1	Outpatient Medical Services in Los Angeles Catchment Area Obligated Amount: $336,523.00 Accounting Info: 7540350 3280075 25.6Z				336,523.00
2	Outpatient Medical Services in Los Angeles Catchment Area Amount: $336,523.00 (Option Line Item) Accounting Info: To be provided upon exercise of option Amount: $336,523.00 (Subject to Availability of Funds) Period of Performance: 01/01/2005 to 12/31/2005				
3	Outpatient Medical Services in Los Angeles Catchment Area Amount: $336,523.00 (Option Line Item) Accounting Info: To be provided upon exercise of option Amount: $336,523.00 (Subject to Availability of Funds) Period of Performance: 01/01/2006 to 12/31/2006 Total amount of award: $1,009,569.00. The obligation for this award is shown in box 15G.				

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. PURPOSE

The purpose of this contract is to provide Outpatient Hansen's Disease (HD) medical services in the Los Angeles Catchment area. There are 532 patients in the area to be served. This contract is in support of the National Hansen's Disease Programs (NHDP), Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), Department of Health and Human Services DHHS. The program is to provide outpatient health care services and support HD outreach in areas with HD patient concentrations and to enable this patient population to access these services. The central goal is to prevent disability through early diagnosis and treatment of HD. The anticipated period of performance is one year with two one-year options, for a total of three years.

B.2. PRICE

The price for services filling the requirements of this contract is a firm fixed price of :

BASE PERIOD Contract award date through December 31, 2004	$336,523.00
OPTION PERIOD ONE January 1, 2005 through December 31, 2005	$336,523.00
OPTION PERIOD TWO January 1, 2006 through December 31, 2006	$336,523.00

In accordance with Section C entitled "DESCRIPTION /SPECIFICATION/WORK STATEMENT" and Section F, entitled "Deliverables or Performance" the contractor is to provide the services contained herein.

B.3. WAGE DETERMINATION

This contract is subject to Wage Determination 1994-2047, Revision 24 dated 6/3/2003, which is included in Section J, Attachment A.

SECTION C – DESCRIPTION /SPECIFICATION/WORK STATEMENT

C.1 Work Statement

Independently and not as an agent of the Government, the contractor shall furnish all personnel, material, facilities, services and equipment as needed to perform the Statement of Work set forth in Section J, Attachment B attached hereto and made a part of this document.

C.2. Incorporation of Contractor's Proposal

It is understood and agreed that the Contractor shall, in meeting the requirements of this contract, perform the work in accordance with the Contractor's proposal to the National Hansen's Disease Programs for Outpatient Hansen's Disease Medical Services, dated November 26, 2003, as amended by revised proposals dated December 15, 2003 and January 5, 2004, provided however, that to the extent that any provisions of the articles of this contract are in conflict or inconsistent with any provisions of said proposal, the provisions of the articles of this contract shall be controlling and shall supersede the provisions of said proposal.

SECTION D – PACKAGING AND MARKING

All reports and documentation required as Deliverables in Section F shall be marked as instructed in Section F of the contract.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

The Project Officer, as a duly authorized representative of the Contracting Officer, shall assume the responsibilities for monitoring the Contractor's performance, evaluating the quality of services provided by the Contractor and performing final inspection and acceptance of all deliverables.

E.2. FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

The contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. In addition, the full text of a clause may be accessed electronically at: http://www.arnet.gov/far/

52.246-4 Inspection of Services – Fixed Price (August 1996)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The initial period of performance of this contract shall be for one year, beginning date of contract award through December 31, 2004, with two one-year options for a total of three years.

F.2. REPORTING REQUIREMENTS AND DELIVERABLES

(1) The contractor shall submit the items in quantities and during the time periods indicated in the schedule of deliverables to the following address:

(Project Officer)
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816

(2) The Contractor shall deliver all items labeled per instructions, and in the quantity cited, and at the time indicated or before the time indicated in this Article.

(a) All deliverable reports are to carry at the top of the first page the following information:

Contract number
Deliverable item number
Deliverable item delivery due date
Date of submission

(b) All deliverables items are to be separate physical entities.

(c) All deliverables are subject to the review and approval of the Project Officer.

(3) Schedule Of Deliverables

Deliverable	Quantity	Due Date
Outpatient Treatment	As required	Upon patient presentation in clinic
Hansen's Disease Surveillance Report	As Needed	Upon confirmed HD Diagnosis
Hansen's Disease Treatment Reporting Form	As Needed	With Annual Report
Biannual Report	1	NLT July 31 (for the reporting period January through June) and NLT January 31 (for the reporting period July through December)
Annual Report	1	NLT 30 days after year end

In addition to the number of copies to be submitted as shown above, one copy of the final report shall be mailed directly to:

National Hansen's Disease Programs
Attn: Contracting Office
1770 Physicians Park Drive
Baton Rouge LA 70816

F.3 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: http:\\www.arnet.gov/far/

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CONTRACT CLAUSES

52.242-15 Stop Work Order (AUG 1989)

SECTION G – CONTRACT ADMINISTRATION

G.1 DESIGNATION OF PROJECT OFFICER

The person identified below is hereby designated as the Government's Project Officer for this contract. The responsibility of the Project Officer -or his duly authorized representative- is to ensure that the Government's technical objectives are met. To this end the Project Officer will provide necessary information, direction, coordination, et cetera, within the contractual work description. Issuance of changes which affect the articles, terms or conditions of this contract will be accomplished through the Contracting Officer who is the only party authorized to bind the Government to contract:

Project Officer: Kathleen Leonard
1770 Physicians Park Drive
Baton Rouge LA 70816
225-756-3759 (Voice)
kdukes@hrsa.gov

The Government may unilaterally change its' designated Project Officer

G.2 KEY PERSONNEL

Pursuant to the Key Personnel clause (HHSAR 352.270-5) referenced in SECTION I of this contract, the following individual(s) is (are) considered to be essential to the work being performed under this contract:

Name	Title
Thomas H. Rea	Physician, Medical Director (Project Director)
Seth Vaccaro	Physician
Jeffrey Ashley	Physician
Helen Baca-Mora	Nursing Care Specialist

The clause cite above contains a requirement for review and approval by the Contracting Officer of written request for change of Key Personnel reasonably in advance of diverting any of these individuals. Receipt of written request at least thirty (30) days prior to a proposed change is considered reasonable.

The person identified above as Project Director shall direct the necessary work and services toward fulfillment of the contractual requirements.

G.3 SUBMISSION OF INVOICES/VOUCHERS

(1) The Contractor may submit invoices monthly. The amount shall be determined by dividing the total annual amount for services by 12. Invoices shall be submitted in an original and one (1) copy to the Project Officer. See Attachment D.

(2) The Contractor shall also, submit two(2) copies of invoices to the following address:

Health and Resources Services Administration
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816
Attn: Contract Specialist
Reference Contract Number: HHSH258200430004C

(3) For inquiries regarding receiving, inspection and acceptance, rejections, or technical issues, call your respective Project Officer.

(4) Contractor agrees to include the following information on its invoice:

a. Contractor's name, invoice number and date;
b. Task order/contract number;
c. Description, price and quantity of services/products delivered;
d. Date of service;
e. Tax identification number;
f. Contractor's complete remittance address; and
g. Signature of an authorized official certifying that the invoice is correct and proper for payment.

(5) Payment Will be Made by:

National Hansen's Disease Programs
Attn: Financial Management Office
1770 Physicians Park Drive
Baton Rouge LA 70816
Telephone Numbers: 225-756-3769

G.4 EVALUATION OF CONTRACTOR'S PERFORMANCE

Interim and final evaluations of Contractor performance shall be conducted on this contract in accordance with FAR Subpart 42.15 and HHSAR 342.7002(c)(2)(iv). Upon contract completion, a final evaluation of the Contractor's performance shall be completed by the Government, see Section J, Attachment C.

	(APR 2003)
52.246-25	Limitation of Liability--Services (FEB 1997)
52.249-2	Termination for Convenience of the Government (Fixed Price) (SEP 1996)
52.249-8	Default (Fixed Price Supplies and Services) (APR 1984)
52.253-01	Computer Generated Forms (JAN 1991)

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CONTRACT CLAUSES

HHSAR Clause No.	Title and Date
352.202-01	Definitions (JAN 2001)
352.224-70	Confidentiality of Information (APR 1984)
352.232-09	Withholding of Contract Payments (APR 1984)
352.242-71	Final Decisions on Audit Findings (APR 1984)
352.270-01	Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (JAN 2001)
352.270-4	Pricing of Adjustments (JAN 2001)
352.270-5	Key Personnel (APR 1984)
352.270-06	Publication and Publicity (JUL 1991)
352.270-07	Paperwork Reduction Act (JAN 2001)

I.2 FAR 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor by the expiration date of the contract.

I.3. 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (NOV 1999)

(a) The Government may extend the term of this contract by written notice to the Contractor within the effective date of the option period, provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months

I.4. 52.204-7Central Contractor Registration

(a) Definitions. As used in this clause-

"Central Contractor Registration (CCR) database" means the primary Government repository for Contractor information required for the conduct of business with the Government.

"Data Universal Numbering System (DUNS) number" means the 9-digit number assigned by Dun and Bradstreet, Inc. (D&B) to identify unique business entities.

"Data Universal Numbering System +4 (DUNS+4) number" means the DUNS number assigned by D&B plus a 4-character suffix that may be assigned by a business concern. (D&B has no affiliation with this 4-character suffix.) This 4-character suffix may be assigned at the discretion of the business concern to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see the FAR at Subpart 32.11) for the same parent concern.

"Registered in the CCR database" means that-

(1) The Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the CCR database; and
(2) The Government has validated all mandatory data fields and has marked the record "Active".

(b)(1) By submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the CCR database prior to award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.
(2) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" or "DUNS +4" followed by the DUNS or DUNS +4 number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number will be used by the Contracting Officer to verify that the offeror is registered in the CCR database.

(c) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.
(1) An offeror may obtain a DUNS number-
(i) If located within the United States, by calling Dun and Bradstreet at 1-866-705-5711 or via the Internet at http://www.dnb.com; or
(ii) If located outside the United States, by contacting the local Dun and Bradstreet office.
(2) The offeror should be prepared to provide the following information:
(i) Company legal business.

(ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(iii) Company Physical Street Address, City, State, and Zip Code.

(iv) Company Mailing Address, City, State and Zip Code (if separate from physical).

(v) Company Telephone Number.

(vi) Date the company was started.

(vii) Number of employees at your location.

(viii) Chief executive officer/key manager.

(ix) Line of business (industry).

(x) Company Headquarters name and address (reporting relationship within your entity).

(d) If the Offeror does not become registered in the CCR database in the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror.

(e) Processing time, which normally takes 48 hours, should be taken into consideration when registering. Offerors who are not registered should consider applying for registration immediately upon receipt of this solicitation.

(f) The Contractor is responsible for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(g) (1) (i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in Subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of Subpart 42.12 of the FAR; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (g)(1)(i) of this clause, or fails to perform the agreement at paragraph (g)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual

payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see FAR Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(h) Offerors and Contractors may obtain information on registration and annual confirmation requirements via the internet at http://www.ccr.gov or by calling 1-888-227-2423, or 269-961-5757.

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

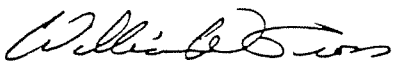
Attachment A Wage Determination 94-2047, Revision 24, Dated 6/3/2003, 10 pages

Attachment B Statement of Work

Attachment C Contractor Past Performance Evaluation

Attachment D Billing Instructions

REGISTER OF WAGE DETERMINATIONS UNDER
THE SERVICE CONTRACT ACT
By direction of the Secretary of Labor



William W. Gross
Director

Division of
Wage Determinations

U.S. DEPARTMENT OF LABOR
EMPLOYMENT STANDARDS ADMINISTRATION
WAGE AND HOUR DIVISION
WASHINGTON, D.C. 20210

Wage Determination No.: 1994-2047
Revision No.: 24
Date of Last Revision: 06/03/2003

State: California

Area: California Counties of Los Angeles, Orange

OCCUPATION NOTES:

Heating, Air Conditioning and Refrigeration: Wage rates and fringe benefits can be found on Wage Determinations 1986-0879.

Laundry: Wage rates and fringe benefits can be found on Wage Determination 1977-1297.

** Fringe Benefits Required Follow the Occupational Listing **

CODE	OCCUPATION TITLE	MINIMUM WAGE RATE
01000	**Administrative Support and Clerical Occupations**	
01011	Accounting Clerk I	10.33
01012	Accounting Clerk II	12.29
01013	Accounting Clerk III	14.79
01014	Accounting Clerk IV	16.28
01030	Court Reporter	16.84
01050	Dispatcher, Motor Vehicle	16.84
01060	Document Preparation Clerk	13.50
01070	Messenger (Courier)	9.28
01090	Duplicating Machine Operator	12.77
01110	Film/Tape Librarian	14.12
01115	General Clerk I	8.87
01116	General Clerk II	10.60
01117	General Clerk III	12.65
01118	General Clerk IV	14.78
01120	Housing Referral Assistant	18.29
01131	Key Entry Operator I	10.32
01132	Key Entry Operator II	12.98
01191	Order Clerk I	12.99
01192	Order Clerk II	14.09
01261	Personnel Assistant (Employment) I	13.70
01262	Personnel Assistant (Employment) II	14.53
01263	Personnel Assistant (Employment) III	18.48
01264	Personnel Assistant (Employment) IV	22.26
01270	Production Control Clerk	17.86
01290	Rental Clerk	14.53
01300	Scheduler, Maintenance	14.53

01311	Secretary I	14.19
01312	Secretary II	17.20
01313	Secretary III	18.29
01314	Secretary IV	21.37
01315	Secretary V	25.48
01320	Service Order Dispatcher	14.51
01341	Stenographer I	13.56
01342	Stenographer II	15.24
01400	Supply Technician	21.37
01420	Survey Worker (Interviewer)	16.84
01460	Switchboard Operator-Receptionist	12.39
01510	Test Examiner	17.02
01520	Test Proctor	17.02
01531	Travel Clerk I	11.20
01532	Travel Clerk II	12.19
01533	Travel Clerk III	13.01
01611	Word Processor I	14.40
01612	Word Processor II	15.40
01613	Word Processor III	17.70
03000	**Automatic Data Processing Occupations**	
03010	Computer Data Librarian	13.98
03041	Computer Operator I	14.53
03042	Computer Operator II	16.84
03043	Computer Operator III	19.53
03044	Computer Operator IV	23.05
03045	Computer Operator V	25.52
03071	Computer Programmer I (1)	17.45
03072	Computer Programmer II (1)	21.88
03073	Computer Programmer III (1)	27.62
03074	Computer Programmer IV (1)	27.62
03101	Computer Systems Analyst I (1)	27.62
03102	Computer Systems Analyst II (1)	27.62
03103	Computer Systems Analyst III (1)	27.62
03160	Peripheral Equipment Operator	15.04
05000	**Automotive Service Occupations**	
05005	Automotive Body Repairer, Fiberglass	21.08
05010	Automotive Glass Installer	19.73
05040	Automotive Worker	19.73
05070	Electrician, Automotive	20.56
05100	Mobile Equipment Servicer	17.77
05130	Motor Equipment Metal Mechanic	21.08
05160	Motor Equipment Metal Worker	19.73
05190	Motor Vehicle Mechanic	21.08
05220	Motor Vehicle Mechanic Helper	16.45
05250	Motor Vehicle Upholstery Worker	18.91
05280	Motor Vehicle Wrecker	19.73
05310	Painter, Automotive	20.56

05340	Radiator Repair Specialist	19.73
05370	Tire Repairer	15.47
05400	Transmission Repair Specialist	21.08
07000	**Food Preparation and Service Occupations**	
	Food Service Worker	8.90
07010	Baker	11.95
07041	Cook I	11.62
07042	Cook II	12.88
07070	Dishwasher	8.06
07130	Meat Cutter	13.15
07250	Waiter/Waitress	8.96
09000	**Furniture Maintenance and Repair Occupations**	
09010	Electrostatic Spray Painter	18.59
09040	Furniture Handler	12.42
09070	Furniture Refinisher	18.59
09100	Furniture Refinisher Helper	14.82
09110	Furniture Repairer, Minor	17.04
09130	Upholsterer	18.59
11030	**General Services and Support Occupations**	
11030	Cleaner, Vehicles	9.64
11060	Elevator Operator	9.59
11090	Gardener	12.62
11121	House Keeping Aid I	8.64
11122	House Keeping Aid II	9.59
11150	Janitor	9.59
11210	Laborer, Grounds Maintenance	10.63
11240	Maid or Houseman	8.64
11270	Pest Controller	13.16
11300	Refuse Collector	9.60
11330	Tractor Operator	11.71
11360	Window Cleaner	11.31
12000	**Health Occupations**	
12020	Dental Assistant	14.77
12040	Emergency Medical Technician (EMT)/Paramedic/Ambulance Driver	14.61
12071	Licensed Practical Nurse I	14.25
12072	Licensed Practical Nurse II	15.96
12073	Licensed Practical Nurse III	17.89
12100	Medical Assistant	12.71
12130	Medical Laboratory Technician	14.37
12160	Medical Record Clerk	12.01
12190	Medical Record Technician	14.48
12221	Nursing Assistant I	8.28
12222	Nursing Assistant II	9.32
12223	Nursing Assistant III	10.16

12224	Nursing Assistant IV	11.41
12250	Pharmacy Technician	14.65
12280	Phlebotomist	12.49
12311	Registered Nurse I	22.91
12312	Registered Nurse II	29.20
12313	Registered Nurse II, Specialist	29.20
12314	Registered Nurse III	35.64
12315	Registered Nurse III, Anesthetist	35.64
12316	Registered Nurse IV	44.19
13000	**Information and Arts Occupations**	
13002	Audiovisual Librarian	18.98
13011	Exhibits Specialist I	22.21
13012	Exhibits Specialist II	27.49
13013	Exhibits Specialist III	30.99
13041	Illustrator I	21.88
13042	Illustrator II	27.11
13043	Illustrator III	30.56
13047	Librarian	25.44
13050	Library Technician	16.27
13071	Photographer I	16.42
13072	Photographer II	19.86
13073	Photographer III	24.61
13074	Photographer IV	27.74
13075	Photographer V	33.56
19000	**Machine Tool Operation and Repair Occupations**	
19010	Machine-Tool Operator (Toolroom)	18.52
19040	Tool and Die Maker	23.95
21000	**Material Handling and Packing Occupations**	
21010	Fuel Distribution System Operator	16.28
21020	Material Coordinator	17.11
21030	Material Expediter	17.11
21040	Material Handling Laborer	11.47
21050	Order Filler	12.38
21071	Forklift Operator	13.69
21080	Production Line Worker (Food Processing)	14.22
21100	Shipping/Receiving Clerk	11.57
21130	Shipping Packer	11.93
21140	Store Worker I	9.38
21150	Stock Clerk (Shelf Stocker; Store Worker II)	12.62
21210	Tools and Parts Attendant	14.35
21400	Warehouse Specialist	14.22
23000	**Mechanics and Maintenance and Repair Occupations**	
23010	Aircraft Mechanic	21.21
23040	Aircraft Mechanic Helper	14.82
23050	Aircraft Quality Control Inspector	22.08

23060	Aircraft Servicer	17.04
23070	Aircraft Worker	17.78
23100	Appliance Mechanic	18.59
23120	Bicycle Repairer	15.47
23125	Cable Splicer	23.50
23130	Carpenter, Maintenance	20.36
23140	Carpet Layer	17.78
23160	Electrician, Maintenance	23.43
23181	Electronics Technician, Maintenance I	17.47
23182	Electronics Technician, Maintenance II	22.81
23183	Electronics Technician, Maintenance III	26.53
23260	Fabric Worker	17.04
23290	Fire Alarm System Mechanic	19.75
23310	Fire Extinguisher Repairer	16.01
23340	Fuel Distribution System Mechanic	19.75
23370	General Maintenance Worker	17.78
23430	Heavy Equipment Mechanic	19.90
23440	Heavy Equipment Operator	24.39
23460	Instrument Mechanic	20.16
23470	Laborer	10.57
23500	Locksmith	18.59
23530	Machinery Maintenance Mechanic	19.75
23550	Machinist, Maintenance	20.17
23580	Maintenance Trades Helper	14.82
23640	Millwright	21.56
23700	Office Appliance Repairer	18.59
23740	Painter, Aircraft	18.59
23760	Painter, Maintenance	18.59
23790	Pipefitter, Maintenance	19.82
23800	Plumber, Maintenance	19.04
23820	Pneudraulic Systems Mechanic	19.75
23850	Rigger	21.90
23870	Scale Mechanic	17.78
23890	Sheet-Metal Worker, Maintenance	19.75
23910	Small Engine Mechanic	17.78
23930	Telecommunication Mechanic I	19.75
23931	Telecommunication Mechanic II	21.41
23950	Telephone Lineman	19.75
23960	Welder, Combination, Maintenance	19.75
23965	Well Driller	20.63
23970	Woodcraft Worker	19.75
23980	Woodworker	16.01
24000	**Personal Needs Occupations**	
24570	Child Care Attendant	11.36
24580	Child Care Center Clerk	14.17
24600	Chore Aid	8.86
24630	Homemaker	16.98

25000	**Plant and System Operation Occupations**	
25010	Boiler Tender	21.49
25040	Sewage Plant Operator	23.26
25070	Stationary Engineer	21.49
25190	Ventilation Equipment Tender	17.08
25210	Water Treatment Plant Operator	21.30
27000	**Protective Service Occupations**	
	Police Officer	29.62
27004	Alarm Monitor	17.77
27006	Corrections Officer	23.16
27010	Court Security Officer	24.80
27040	Detention Officer	23.16
27070	Firefighter	24.37
27101	Guard I	8.51
27102	Guard II	17.77
28000	**Stevedoring/Longshoremen Occupations**	
28010	Blocker and Bracer	17.46
28020	Hatch Tender	17.46
28030	Line Handler	17.46
28040	Stevedore I	17.90
28050	Stevedore II	19.48
29000	**Technical Occupations**	
21150	Graphic Artist	23.34
29010	Air Traffic Control Specialist, Center (2)	31.08
29011	Air Traffic Control Specialist, Station (2)	21.43
29012	Air Traffic Control Specialist, Terminal (2)	23.60
29023	Archeological Technician I	18.35
29024	Archeological Technician II	20.53
29025	Archeological Technician III	25.44
29030	Cartographic Technician	28.74
29035	Computer Based Training (CBT) Specialist/ Instructor	25.67
29040	Civil Engineering Technician	25.24
29061	Drafter I	17.40
29062	Drafter II	19.52
29063	Drafter III	23.58
29064	Drafter IV	29.26
29081	Engineering Technician I	14.74
29082	Engineering Technician II	16.56
29083	Engineering Technician III	19.43
29084	Engineering Technician IV	23.66
29085	Engineering Technician V	27.13
29086	Engineering Technician VI	32.84
29090	Environmental Technician	21.05
29100	Flight Simulator/Instructor (Pilot)	30.38

29160	Instructor	24.35
29210	Laboratory Technician	16.69
29240	Mathematical Technician	24.77
29361	Paralegal/Legal Assistant I	16.63
29362	Paralegal/Legal Assistant II	19.57
29363	Paralegal/Legal Assistant III	23.88
29364	Paralegal/Legal Assistant IV	28.98
29390	Photooptics Technician	21.21
29480	Technical Writer	27.46
29491	Unexploded Ordnance (UXO) Technician I	19.75
29492	Unexploded Ordnance (UXO) Technician II	23.90
29493	Unexploded Ordnance (UXO) Technician III	28.64
29494	Unexploded (UXO) Safety Escort	19.75
29495	Unexploded (UXO) Sweep Personnel	19.75
29620	Weather Observer, Senior (3)	20.99
29621	Weather Observer, Combined Upper Air and Surface Programs (3)	18.88
29622	Weather Observer, Upper Air (3)	18.88
31000	**Transportation/ Mobile Equipment Operation Occupations**	
31030	Bus Driver	15.41
31260	Parking and Lot Attendant	7.80
31290	Shuttle Bus Driver	12.23
31300	Taxi Driver	10.52
31361	Truckdriver, Light Truck	12.23
31362	Truckdriver, Medium Truck	16.95
31363	Truckdriver, Heavy Truck	18.12
31364	Truckdriver, Tractor-Trailer	18.12
99000	**Miscellaneous Occupations**	
99020	Animal Caretaker	9.21
99030	Cashier	11.33
99041	Carnival Equipment Operator	11.01
99042	Carnival Equipment Repairer	11.86
99043	Carnival Worker	8.35
99050	Desk Clerk	12.65
99095	Embalmer	19.16
99300	Lifeguard	10.38
99310	Mortician	21.33
99350	Park Attendant (Aide)	13.03
99400	Photofinishing Worker (Photo Lab Tech., Darkroom Tech)	13.64
99500	Recreation Specialist	16.23
99510	Recycling Worker	12.66
99610	Sales Clerk	10.71
99620	School Crossing Guard (Crosswalk Attendant)	8.87
99630	Sport Official	10.38
99658	Survey Party Chief (Chief of Party)	28.47
99659	Surveying Technician (Instr. Person/Surveyor Asst./Instr.)	21.43

99660	Surveying Aide	15.66
99690	Swimming Pool Operator	13.74
99720	Vending Machine Attendant	11.51
99730	Vending Machine Repairer	13.74
99740	Vending Machine Repairer Helper	11.51

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: $2.36 an hour or $94.40 a week or $409.07 a month

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or successor; 3 weeks after 5 years, and 4 weeks after 15 years. Length of service includes the whole span of continuous service with the present contractor or successor, wherever employed, and with the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of ten paid holidays per year: New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitute for any of the named holidays another day off with pay in accordance with a plan communicated to the employees involved.) (See 29 CFR 4.174)

THE OCCUPATIONS WHICH HAVE PARENTHESES AFTER THEM RECEIVE THE FOLLOWING BENEFITS (as numbered):

1) Does not apply to employees employed in a bona fide executive, administrative, or professional capacity as defined and delineated in 29 CFR 541. (See CFR 4.156)

2) APPLICABLE TO AIR TRAFFIC CONTROLLERS ONLY - NIGHT DIFFERENTIAL: An employee is entitled to pay for all work performed between the hours of 6:00 P.M. and 6:00 A.M. at the rate of basic pay plus a night pay differential amounting to 10 percent of the rate of basic pay.

3) WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a regular tour of duty, you will earn a night differential and receive an additional 10% of basic pay for any hours worked between 6pm and 6am. If you are a full-time employed (40 hours a week) and Sunday is part of your regularly scheduled workweek, you are paid at your rate of basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday work which is not overtime (i.e. occasional work on Sunday outside the normal tour of duty is considered overtime work).

HAZARDOUS PAY DIFFERENTIAL: An 8 percent differential is applicable to employees employed in a position that represents a high degree of hazard when working with or in close proximity to ordinance, explosives, and incendiary materials. This includes work such as screening, blending, dying, mixing, and pressing of sensitive ordance, explosives, and pyrotechnic compositions such as lead azide, black powder and photoflash powder. All dry-house activities involving propellants or explosives. Demilitarization, modification, renovation, demolition, and maintenance operations on sensitive ordnance, explosives and incendiary materials. All operations involving regrading and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that represents a low degree of hazard when working with, or in close proximity to ordance, (or employees possibly adjacent to) explosives and incendiary materials which involves potential injury such as laceration of hands, face, or arms of the employee engaged in the operation, irritation of the skin, minor burns and the like; minimal damage to immediate or adjacent work area or equipment being used. All operations involving, unloading, storage, and hauling of ordance, explosive, and incendiary ordnance material other than small arms ammunition. These differentials are only applicable to work that has been specifically designated by the agency for ordance, explosives, and incendiary material differential pay.

** UNIFORM ALLOWANCE **

If employees are required to wear uniforms in the performance of this contract (either by the terms of the Government contract, by the employer, by the state or local law, etc.), the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) such uniforms is an expense that may not be borne by an employee where such cost reduces the hourly rate below that required by the wage determination. The Department of Labor will accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequate number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsibility of the employee, all contractors and subcontractors subject to this wage determination shall (in the absence of a bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual cost), reimburse all employees for such cleaning and maintenance at a rate of $3.35 per week (or $.67 cents per day). However, in those instances where the uniforms furnished are made of "wash and wear" materials, may be routinely washed and dried with other personal garments, and do not require any special treatment such as dry cleaning, daily washing, or commercial laundering in order to meet the cleanliness or appearance standards set by the terms of the Government contract, by the contractor, by law, or by the nature of the work, there is no requirement that employees be reimbursed for uniform maintenance costs.

** NOTES APPLYING TO THIS WAGE DETERMINATION **

Source of Occupational Title and Descriptions:

The duties of employees under job titles listed are those described in the "Service Contract Act Directory of Occupations," Fourth Edition, January 1993, as amended by the Third Supplement, dated March 1997, unless otherwise indicated. This publication may be obtained from the Superintendent of Documents, at 202-783-3238, or by writing to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Copies of specific job descriptions may also be obtained from the appropriate contracting officer.

REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE {Standard Form 1444 (SF 1444)}

Conformance Process:

The contracting officer shall require that any class of service employee which is not listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), be classified by the contractor so as to provide a reasonable relationship (i.e., appropriate level of skill comparison) between such unlisted classifications and the classifications listed in the wage determination. Such conformed classes of employees shall be paid the monetary wages and furnished the fringe benefits as are determined. Such conforming process shall be initiated by the contractor prior to the performance of contract work by such unlisted class(es) of employees. The conformed classification, wage rate, and/or fringe benefits shall be retroactive to the commencement date of the contract. {See Section 4.6 (C)(vi)} When multiple wage determinations are included in a contract, a separate SF 1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

1) When preparing the bid, the contractor identifies the need for a conformed occupation(s) and computes a proposed rate(s).

2) After contract award, the contractor prepares a written report listing in order proposed classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), including information regarding the agreement or disagreement of the authorized representative of the employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later than 30 days after such unlisted class(es) of employees performs any contract work.

3) The contracting officer reviews the proposed action and promptly submits a report of the action, together with the agency's recommendations and pertinent information including the position of the contractor and the

employees, to the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, for review. (See section 4.6(b)(2) of Regulations 29 CFR Part 4).

4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disapproves the action via transmittal to the agency contracting officer, or notifies the contracting officer that additional time will be required to process the request.

5) The contracting officer transmits the Wage and Hour decision to the contractor.

6) The contractor informs the affected employees.

Information required by the Regulations must be submitted on SF 1444 or bond paper.

When preparing a conformance request, the "Service Contract Act Directory of Occupations" (the Directory) should be used to compare job definitions to insure that duties requested are not performed by a classification already listed in the wage determination. Remember, it is not the job title, but the required tasks that determine whether a class is included in an established wage determination. Conformances may not be used to artificially split, combine, or subdivide classifications listed in the wage determination.

ATTACHMENT B STATEMENT OF WORK

A. General Description

The purpose of this contract is to provide outpatient treatment for individuals with Hansen's Disease, case management and follow-up of the HD patients and screening of their close contacts; provide information and in-service education about HD to healthcare providers in the community, and to serve as HD consultant and resource in the community in the Los Angeles area as described below. The contractor shall provide all personnel, material, adequate and accessible facilities, services, and equipment required to meet the requirements of this contract.

Presently, 532 patients with HD are being treated in the Los Angeles area. On the basis of experience, it is estimated that these patients will require 4 outpatient visits annually during the period of this contract.

B. Background Information

The legislative authority for the National Hansen's Disease Programs is Public Law 99-117, Section 2.(a.), Section 320, and is guided by DHHS regulations. The Ambulatory Care Program was initiated in 1981 as a consequence of the closing of the U.S.P.H.S. hospitals. Historically, persons with HD were provided care by those facilities in the U.S. In order to continue the mandate of the legislative authority, a Contract Care Program was developed to provide these services in communities where the majority of people with HD lived. Those geographic areas are reflected by the location of the current Outpatient HD Clinics. In 1994, the Contract Care Program was converted to grants. As of September 29, 2003, the grant program has now been converted to a Contract Care Program.

Hansen's disease in the United States occurs primarily in California, Louisiana, New York, Puerto Rico, and Texas, and among Asian and Hispanic populations in these areas.

C. Technical Requirements

1. The contractor shall be responsible for providing outpatient care as described herein to those persons designated as eligible for treatment. The contractor shall be responsible for validating the patient's eligibility before rendering services. Patients are considered eligible under the following circumstances:

a. HD Patient - Any individual in the continental United States and Territory of Puerto Rico who has been diagnosed as having Hansen's disease is automatically eligible for care under this contract.

b. HD Contact - Any person who has lived in the same household with a new HD patient in the three year period prior to the diagnosis and the beginning of treatment, shall be examined. If the index case has Paucibacillary disease, only an initial contact exam is necessary. For index cases who have Multibacillary disease, it is recommended that their contacts have annual examinations for at least 5 years.

c. HD Suspect - Individuals suspected of having HD may be referred to the contractor by other physicians or health care agencies. These individuals will be provided with services required to rule out the disease.

When the eligibility status of an individual patient is unclear, the contractor will obtain guidance and approval from the project officer.

2. Outpatient Care

Evaluation of a patient with suspected or confirmed HD shall include a complete history and physical exam as outlined in the Standards Of Care (see Appendix) for Hansen's Disease in the United States.

a. Required Tasks

(1) Target population- Any patient living in the continental United States or Puerto Rico may receive outpatient medical care for the diagnosis and treatment of HD and its related conditions. Contacts of these patients are also eligible to receive this care, according to the policies set below.

Healthcare providers working with populations from endemic countries must be targeted for educational services about HD in order to raise their index of suspicion for this disease among their client population.

(2) Required Services-The purpose of the Outpatient Hansen's Disease Program is to provide outpatient medical and diagnostic services for HD and its related conditions to persons in the continental United States and Puerto Rico. The Contractor shall provide hours of operation adequate to support the HD patient population in the area served and provide arrangement for after hours care (e.g. answering service). These services must be provided in a culturally appropriate and competent manner.

The Treatment Protocol for Hansen's Disease in the U.S. is multi-drug therapy which includes the drugs Dapsone, Rifampin and Clofazimine. This protocol is outlined in the Standards of Care.

Services to be provided through this contract, according to the following protocol, include:

(a) Patient Assessment:

Hansen's disease affects the skin, peripheral nerves, anterior part of the eyes, and the nasal area. In the advanced form of the disease (Lepromatous leprosy), it can cause gynecomastia and testicular atrophy in males. A complete physical assessment of the patient is necessary. Diagnostic criteria include the presence of anesthetic lesions with M.

leprae in skin smears or biopsies, and sometimes, peripheral nerve enlargement.

Eyes: Examine the eye for inflammation, complete closure, and pupil size. In patients with borderline lepromatous or lepromatous disease, an ophthalmological exam shall be done to rule out eye involvement in this disease.

Skin: Hypo- or hyper-pigmented flat or raised lesions, are most commonly found on the face, extremities, buttocks, or thighs. Absence of sweating, hair loss, or changes in texture of the skin may also be present.

Nerves: Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are most commonly affected. In patients with anesthesia of the hands or feet, ulcerations, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.

(b) Diagnostic Studies:

- Punch Biopsy: A 4 mm punch biopsy or larger is needed for diagnosis.

- Skin smears: These may be done on initial exam on all patients, and annually on all Multibacillary patients for a total of 8 years. See Appendix.

(c) Laboratory Monitoring:

- Schedule

Drug	Laboratory Test	Frequency
All drugs	CBC with platelet Count,UA,Chem 20, G6PD	Baseline
Dapsone	G6PD,CBC	Baseline Every six months
Rifampin	CBC with platelet count,Chem 20	Every six months
Clofazimine	No requirements	
Thalidomide	CBC with differential	Every three months

- Other tests

1. UA (urinary analysis) shall be done annually with these studies for all patients.

2. PCR Assay(Polymerase Chain Reaction)
In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify M.leprae when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy.(Am J Clin Pathol 1998; 109:642-646) To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief of Pathology, Research Department,
NHDP, at 225-346-5769.

(d) Treatment

The Standards of Care in Appendix provide guidelines which shall be used to determine treatment of Hansen's disease under this contract.

(e) Consultant Services

Due to the multi-faceted aspects of this disease, patients shall be referred to the following ancillary medical services for treatment of complications as necessary:

(1) ENT
(2) Occupational Therapy
(3) Ophthalmology
(4) Orthopedics
(5) Orthotics
(6) Physical Therapy
(7) Podiatry

Clinical consultations with staff at the National Hansen's Disease Programs are available by calling 1-800-642-2477.

(f) Rehabilitation Services

Disability prevention is promoted by the visual inspection of the eyes, hands, and feet of the patient at each encounter. If the hand or foot require further evaluation, a hand or foot screen and palpation of the nerves shall be done. (See Appendix, Standards of Care for procedures.)

For patients scheduled to receive care at the NHDP in Baton Rouge, the Ambulatory Care therapist coordinates care with the NHDP therapists. Preoperative casting, wound care and post operative rehabilitation provided by the therapist in the Ambulatory Care setting decreases the length of stay required for care at the NHDP.

(1) Eye – Ophthalmological services are needed for persons with paucibacillary disease who may have incomplete palpebral closure or loss, corneal sensation and for those with multibacillary disease have infiltration of the anterior part of the eye with HD bacilli. Patients with eye complaints shall be referred to the ophthalmologist.

(2) Occupational Therapy– Services required for the performance of this contract include performing hand screens and reporting changes in sensory and motor function to the physician, teaching prevention of disability, providing wound care, fabricating splints and casts, recommending assistive devices, rehabilitation tendon transfers and other orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.

- Hand Screens - These are a means of assessing the HD patient's risk category for hand problems, and for developing a care plan for their prevention and treatment.

The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measure levels of cutaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

(3) Physical Therapy services include the following:

- Foot Screens - The Foot Screen has been proven to accurately identify patients who are at risk of developing deformities as a result of insensitivity, and also provides a baseline for determining the extent of foot disabilities.

The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder is designed to deliver a 10 gram force when properly applied. Our research has shown that a patient who can feel the 10 gram filament in the selected sites will not develop ulcers.

(4) Frequency of performance:

(a) Hand and foot screens shall be done for new patients at the time of diagnosis

(b) Annually until stable for 3 years. During reactions or neuritis, screens shall be done more frequently as clinically indicated.

(c) After 3 years, annually until skin smear negative

The hand and foot filament sets for the Ambulatory Care Clinics may be obtained by calling 1-800-642-2477.

(5) Hand And Foot Rehabilitation

An efficient and comprehensive rehab program, in the management of insensitive limbs shall incorporate physical therapy, occupational therapy, pedorthics, and patient education. Rehabilitation goals aimed at minimizing loss of function, ulceration, amputation, and ultimate disability, can be satisfactorily achieved utilizing the following interdisciplinary rehab practices: hand & foot care, exercise, wound care, foot care, splinting, casting, and electromyography.

(e) Inpatient Care - Medical staff in Baton Rouge may authorize an inpatient admission to the NHDP at Summit Hospital, Baton Rouge, Louisiana, on a case-by-case basis.

(f) Leprosy Surveillance Form - All newly diagnosed cases of HD shall be documented on a Hansen's Disease Surveillance Form.

(g) HD Contact Surveillance - Any person who has lived in the same household with a new HD patient in the three year period prior to the diagnosis and the beginning of treatment, shall be examined. If the index case has Tuberculoid disease, only an initial contact exam is necessary. For index cases who have Borderline Lepromatous or Lepromatous HD, it is recommended that their contacts have annual examinations for at least 5 years.

(h) Patient and Professional Education - Appropriate treatment of a stigmatizing disease like HD involves concerns about deformity, disability, isolation, job loss, and being a source of infection to their families. Awareness of these patient concerns will more likely ensure patient compliance with treatment.

In order to achieve its objective, which is the prevention of deformity and disability, the patient assessment, hand and foot screens, HD monitors, and contact exam shall be used to educate patients and family about HD.

The majority of healthcare providers in the U.S. are not aware of HD in the population. Providers serving populations from endemic countries shall be targeted for educational services on HD in order to increase their index of suspicion for HD.

Educational materials are available from the NHDP (See "Resources" in the Standards of Care in the Appendix).

(i) Patient Transportation - Reimbursement for travel to the HD Clinics shall be provided through this contract for indigent patients when it is deemed necessary by the HD clinic staff.

(j) Self –Evaluation – Contractors shall include a self-evaluation plan that involves monitoring the implementation of the program and compliance with the Standards of Care. These program monitoring/self-evaluation activities shall not require the services of outside evaluators or consultants.

The process of program implementation, evaluation, program changes, and re-evaluation are an integral component of good management, and shall be an essential part of each contractor's activities. Baseline data shall be collected for the preliminary needs assessment and for the life of the contract to support consistent comparison within the service population. Contractors are expected to get feedback while the activities are being implemented, and determine and make appropriate mid-course adjustment. Each intervention shall be evaluated in terms of the extent to which it improves the availability, accessibility, acceptability, and risk appropriateness of care.

(k) The contractor shall provide all necessary health services related to HD either directly or through subcontractors. The contractor is responsible for payments to subcontractors.

(l) Medical Records – The contractor shall have adequate systems in place to ensure the confidentiality of patient medical records.

(3) Reference Material

The Standards of Care in the appendix provide guidelines for treatment of Hansen's disease in the U.S.

Copies of the protocols, reporting forms, and consent forms are available from the National Hansen's Disease Program . Questions regarding treatment regimens shall be directed to the Clinical Branch at NHDP.

(4) The multidisciplinary team that will provide services through the HD program in this contract are considered to be essential to the work being performed. The Director, ACP, must be notified of changes in key personnel, and CVs submitted on any of these who are replaced.

Project Director:
Primary Physician:
HD Clinic RN:

It is estimated that a routine, uncomplicated patient visit for HD services can be completed in 20 minutes, and visit frequency for the monitoring of chemotherapy is an average of four times a year. New cases may require 40 minutes to an hour for assessment. About 150 - 200 new cases are diagnosed each year in the United States. It is estimated that 20% of the patient population may have complications such as ulcers, reaction, eye, hand, or foot problems which require more time during a clinic visit.

Providers shall be licensed to practice, certified in their specialty, culturally competent, experienced in caring for the targeted population, and have appropriate consultative back up. This team shall include:

a. Physician (part-time)
b. Nurse (part-time)
c. ENT (as needed)
d. Occupational therapist (as needed)
e. Physical therapist (as needed)
f. Orthopedist (as needed)
g. Orthotist (as needed)
h. Podiatrist (as needed)
i. Ophthalmologist (as needed)

(5) Reporting Requirements (See Appendix, Standards of Care for forms)

a. A Hansen's Disease Surveillance Form shall be completed on all newly-diagnosed patients as soon as the diagnosis is confirmed.

b. HD Treatment Reporting Form shall be completed upon initiation of therapy

c. The contractor shall submit biannually an electronic report on diskette generated with the use of Microsoft Access or compatible database NLT July 31 (for the reporting period January through June) and NLT January 31 (for the reporting period July through December) containing the following information

1. Name of all patients, birth date, social security number, and address
2. Number of clinic visits, if any, for each patient during the reporting period
3. HD medications each patient is receiving and start date
4. Type and number of consultant visits (OT, PT, etc.) per patient during the reporting period
5. Hard copy of all hand and foot screens performed during the reporting period

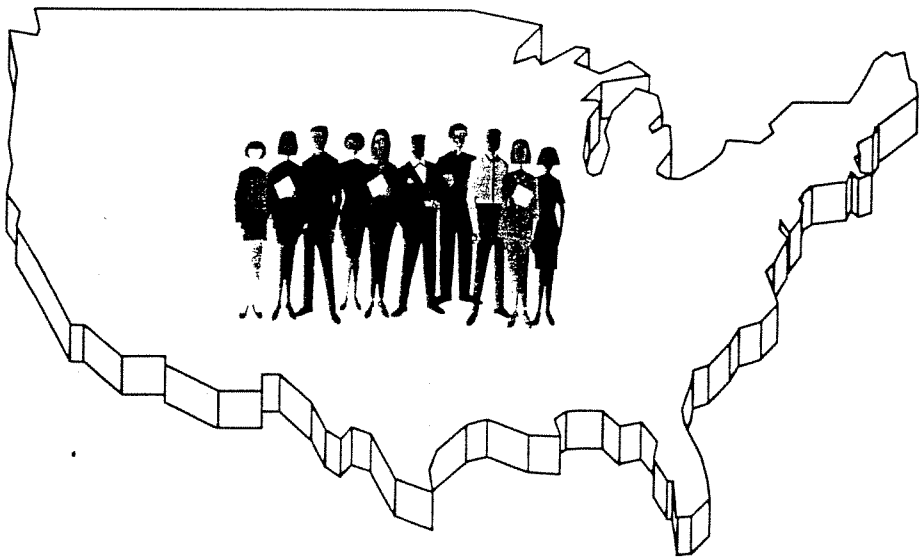
d. Annual Report:

1. Report of all deceased patients, including birth date, social security number, date and cause of death, if known
2. Follow-up HD Treatment reporting form
3. Thalidomide report
4. A brief description of the annual independent audit. If deficiencies were identified, note them and how they were corrected and addressed.

e. Other reports and information to be determined by the project officer as part of an ongoing evaluation program to determine the effectiveness of the care provided under this contract.

APPENDIX – STANDARDS OF CARE

STANDARDS OF CARE FOR HANSEN'S DISEASE IN THE UNITED STATES



NATIONAL HANSEN'S DISEASE PROGRAMS
Ambulatory Care Program
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816
1-800-642-2477

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NATIONAL HANSEN'S DISEASE PROGRAMS

STANDARDS OF CARE FOR HANSEN'S DISEASE IN THE UNITED STATES

INTRODUCTION

MISSION

The National Hansen's Disease Program (NHDP) is an activity in the Department of Health and Human Services (DHHS), and the Bureau of Primary Health Care (BPHC). It is authorized by Public Law 99-117, Section 2. (a), Section 320 and is guided by DHHS regulations. The NHDP is charged with the responsibility of providing Hansen's disease (HD) treatment for individuals with this disease through the NHDP, in Baton Rouge, Louisiana, and through its Ambulatory Care Program.

ELIGIBILITY

Any individual living in the United States and Puerto Rico may receive outpatient medical care for the diagnosis and treatment of HD and its complications. Contacts of these patients are also eligible for services as described by NHDP policy.

OBJECTIVE

The goal of the Ambulatory Care Program is to prevent deformity and disability from HD through early diagnosis and treatment. The purpose of this Manual is to serve as a resource for the Standards of Care in the treatment of HD in the United States (U.S.).

HISTORY

The NHDP in the United States has a 100-year history of caring for people diagnosed with this disease. It began in 1896 at an abandoned plantation home in Carville, Louisiana, with the Daughters of Charity of St.Vincent de Paul from the state of Maryland as volunteers. They provided basic services to a small group of patients from the city of New Orleans, and continued through the development of the federally-funded Gillis W. Long Hansen's Disease Center in Carville. The Center became the only inpatient facility for HD in the country.

In the early 40's, the use of sulfone therapy by Dr. Guy Faget resulted in the development of dapsone as a bactericidal agent against Mycobacterium leprae, the mycobacteria that causes the disease. This led to the greatest change in patient care, for patients could now be discharged from "Carville" and new patients treated as outpatients. The year 1960 saw the initiation of rehabilitative procedures introduced by Dr. Paul Brand, an orthopedic surgeon, which have effectively decreased the frequency of amputation of the lower extremities. In the 1970's, rifampin was added to the multi-drug regimen that is the recommended therapy in the U.S.

NATIONAL HANSEN' DISEASE PROGRAM

In 1981, the Federal Government initiated the Ambulatory Care Program, which provides HD medical care throughout Outpatient Clinics in various facilities located where most of the patients live in the U.S. and Puerto Rico. Services provided by these Clinics include diagnosis and treatment of HD and related conditions, laboratory monitoring, consultant services, and patient and community education.

For budgetary reasons, the Federal Government transferred the facility at Carville to the State of Louisiana in 1999. Ambulatory residential patients were permitted to stay at Carville if they wished, with outpatient medical services provided there. Long-term, residential patients requiring continuous nursing services were relocated to the Hansen's Unit at Summit Hospital in Baton Rouge, Louisiana. Patients referred by the Outpatient HD Clinics or by private physicians are also admitted to Summit Hospital.

PRIVATE PHYSICIAN PROGRAM

HD medications can be provided to patients living in an area not served by an HD clinic. Their private physician can order the HD medications (dapsone, rifampin, clofazimine) from the NHDP at no charge to the patient. Consultant and biopsy processing services are also provided to the physician, and a patient may be referred to the NHDP in Baton Rouge upon consultation with the medical staff. Transportation assistance to Summit Hospital may be available if necessary.

EPIDEMIOLOGY

In the United States, HD occurs primarily in California, Hawaii, Louisiana, New York, Puerto Rico, and Texas, which are considered endemic areas for the disease.

The disease is usually diagnosed between the ages of 20-75, with a ratio of 2:1 males to females. Annually, there are about 150-200 new cases of HD diagnosed in the U.S. These demographics have been fairly consistent over time. The index of suspicion for HD must be high for a person who lives in an endemic area of the U.S. or may have come from an endemic country.

BACTERIOLOGY

HD is caused by Mycobacterium leprae, a slow-growing, acid-fast bacillus. The incubation period for HD may be two-five years, although it can be as long as 15-20 years or more. The disease is probably spread through airborne droplets from the nasal mucosa and upper airways of a person with untreated disease, or through prolonged skin contact with this person. Armadillos may also carry the disease. The communicability of HD is very low, however, and about 95% of the world's population has a natural immunity to this bacillus. A person with HD becomes non-communicable within one week of starting treatment.

MANAGEMENT OF HANSEN'S DISEASE

CLINICAL PRESENTATION

HD affects the skin, peripheral nerves, eyes, and mucous membranes of the upper respiratory tract, especially the nose. Nerve damage caused by the bacillus may result in anesthesia and deformities of the hands and feet and lagophthalmos of the eyes. In lepromatous HD there may be iritis, direct invasion of the anterior part of the eye by the bacilli, and in males, it may cause testicular atrophy and gynecomastia. A complete physical assessment of the patient is necessary.

In most people, resistance develops to infection with M.leprae. The body's defenses kill the invading bacteria, or contain the infection so disease does not develop. In persons with limited or no resistance to the disease, the bacteria grow slowly, eventually leading to the appearance of symptoms. Presence of the bacteria will be demonstrated with skin smears or biopsy.

Hypo- or hyper-pigmented, flat or raised lesions appear which may be insensitive to light touch. These most commonly appear on the buttocks, thighs, trunk, and lateral aspect of the upper and lower extremities. There may be anhidrosis, loss of hair on the skin, excluding the scalp, and changes in skin texture. The earlobes may be swollen and pendulous.

Patients may experience inflammation of the eyes, excessive or decreased tearing, loss of lateral eyebrows, and incomplete closure of the eyelids, and loss of corneal sensation.

Muscle strength of the hands and feet may be affected. There may be dryness, decreased sensation, muscle atrophy, deformity such as clawing of fingers or toes, wounds, and ulcers. Male patients may have painful, swollen testicles or gynecomastia.

Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, peroneal, and greater auricular are most commonly affected. Some patients complain of pain in the extremities, and a burning sensation in the soles of the feet. Abnormal nerves will feel sclerosed.

HD AND PREGNANCY

A female with HD who is pregnant is rare in the U.S., but a few cases occur each year. The majority of these pregnancies are uneventful as far as HD is concerned, but there are a number of potential problems and risks that should be considered when advising female HD patients of childbearing age, and when managing patients who are already pregnant and have HD.

All female patients of childbearing age should be advised to avoid pregnancy during early stages of the disease, at least until MDT has been completed and preferably until the disease is completely inactive. The postponement of pregnancy is especially important for patients who have evidence of reaction or neuritis since these problems will be exacerbated during pregnancy and the postpartum period. There may also be a very small risk of transmission of the disease from mother to infant in those cases where the pregnancy occurs before treatment or early in the course of treatment.

There are alterations in the immune response during all pregnancies, causing a depression of the cell-mediated immune system. This immune suppression during pregnancy and its recovery in the postpartum period appears to play a role in the clinical manifestations of HD in women. It is common for the first symptoms of HD in young women to occur during pregnancy or the postpartum period. An increased risk of relapse during pregnancy has also been reported.

ENL is more common during pregnancy when the CMI is depressed, while reversal reaction is more common during the postpartum period when the CMI is recovering.

The risk of reactions or neuritis during pregnancy will vary considerably with the type of disease and the amount of treatment a patient has received prior to the pregnancy. If a reaction occurs during a pregnancy, it should be managed as in non-pregnant patients with the use of prednisone sufficient to control the reaction and prevent nerve damage. Thalidomide cannot be used.

For patients who are or become pregnant during the early stages of the disease, chemotherapy should generally continue during pregnancy with some modification of the regimens in some cases. We avoid the use of rifampin during pregnancy if possible. Dapsone and/or clofazimine can be continued throughout the pregnancy.

Patients who have had HD some time in the past, who have been adequately treated, and whose disease is now completely inactive, can be expected to have essentially normal pregnancies. There is no risk of the mother transmitting the disease to infants in such cases.

HD AND CHILDREN

HD in children is uncommon in the U.S., but does occur and is usually indeterminate or tuberculoid type disease. It is usually a benign disease with very few deformities reported. Management of the disease is generally the same as for adults except for the adjustment of drug dosages to be determined by the physician. Transmission of HD to children should not occur after the adult patient starts on treatment that includes rifampin. Preventive treatment is not generally recommended for child contacts. The presence of new cases in children usually indicates that HD is still being transmitted in the general population.

TESTICULAR HD

Direct invasion of the testicles probably occurs in most cases of Borderline and Lepromatous disease, although testicular dysfunction is most common in Lepromatous disease. The testicles are a cool part of the body and are preferentially affected. If HD is not treated early, there is progressive destruction of testicular tissue and eventually testicular atrophy with sterility and a decrease in testosterone production.

Gynecomastia usually develops relatively late and is an indication of advanced disease. Acute orchitis may develop during ENL and may be an indication for prednisone therapy. Testicular atrophy is usually permanent. After testicular function is destroyed, the only treatment is testosterone replacement. This does not restore fertility but is helpful in restoring sexual potency. Injectables are the preferred route for replacement therapy. Oral androgens are not recommended for long-term therapy because of potential liver toxicity.

DIAGNOSTIC CRITERIA

The presence of anesthetic skin lesions with acid-fast bacilli in skin smears or biopsies are diagnostic of HD. Sometimes enlarged peripheral nerves may also be present.

SCHEDULE OF SERVICES

I. New Patient
   - A. Patient Interview
   - B. HD Monitors
   - C. Medical Assessment
   - D. Biopsy
   - E. Skin Smears (optional)
   - F. Baseline laboratory studies
   - G. Hand and Foot Screens
   - H. HD New patient Treatment Form
   - I. HD Surveillance Form
   - J. HD Patient Education

II. Follow-Up Visit
   - A. Patient Interview
   - B. HD Monitors
   - C. Medical Assessment
   - D. Laboratory monitoring every three months or as necessary
   - E. Skin Smears annually (optional)
   - F. Hand and Foot Screens every six months or as necessary
   - G. Treatment Follow-Up Forms
   - H. Patient Education every clinic visit

PATIENT ASSESSMENT

I. Patient Interview
   - A. Family History of HD
   - B. Presenting Symptoms
     1. No pain reported with injuries such as cuts or burns
     2. Recurrent nosebleeds
     3. Chronic nasal congestion
     4. Burning sensation on soles of feet or hands
     5. Painful / tender peripheral nerves
   - C. Psychological considerations
     1. Stigma/myths
     2. Sharing diagnosis-family, friends, boss, colleagues
     3. Common concerns-cause, treatment, contagiousness, transmission through sex, deformities
   - D. Teaching Plan
     1. Address patient concerns
     2. Treatment, length, medication side-effects
     3. Prognosis, prevention of deformity, reaction
     4. Refer to support group (e.g., IDEA)
   - E. Standards for Performance
     1. First interview should include all elements above with initiation of D., Teaching Plan
     2. Follow-up visits should include B., C., and continuation of D.

II. Physical Assessment
   - A. Skin-It is important to perform a complete examination of the skin in good light. Hypopigmented of hyperpigmented flat or raised lesions may be found on the face, trunk, extremities, buttocks, or thighs. Absence of sweating, hair loss, or changes in texture of the skin may also be present. Ask male patients about pain or swelling of the testicles and examine for erythematous nodules.
   - B. Eyes-Examine the eyes for the inflammation, incomplete closure of the eyelids, and pupil size. In patients with borderline lepromatous disease, an ophthalmological exam should be done to rule out eye involvement.
   - C. Nerves-A peripheral nerve assessment should be done to determine if nerves are enlarged or tender (See Appendix).The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are commonly affected. In patients with anesthesia of the hands or feet, ulcerations, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.
   - D. Hands and Feet-Hands and feet should be examined for dryness, diminished sensation, muscle weakness or muscle atrophy, wounds, and ulcers.

E. HD Monitors-The purpose of this exam is to perform a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. It is an excellent venue for teaching patients about the prevention of complications. (See Appendix for procedure)

F. Performance Standard
   1. Loss of sensation associated with a lesion requires a biopsy be performed to diagnose HD
   2. HD Monitors should be performed at each patient visit
   3. Patients with borderline or lepromatous disease should have an initial ophthalmological exam
   4. Patients with hand or foot problems should have hand and foot screens done, and referred as necessary

LABORATORY MONITORING

I. Schedule

Drug	Laboratory Test	Frequency
All drugs	CBC with platelet Count, UA, Chem 20, G6PD	Baseline
Dapsone	G6PD, CBC	Baseline Every six months
Rifampin	CBC with platelet count, Chem 20	Every six months
Clofazimine	No requirements	
Thalidomide	CBC with differential	Every three months

II. Other tests
   A. UA should be done annually with these studies for all patients.
   B. PCR Assay(Polymerase Chain Reaction)
   In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify M.leprae when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy.(Am J Clin Pathol 1998; 109:642-646) To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief of Pathology, Research Department, NHDP, at 225-346-5769.

C. Performance Standard

1. Baseline laboratory studies are performed on all patients before initiation of chemotherapy
2. Follow-up laboratory monitoring is done quarterly on patients receiving MDT which includes rifampin
3. Other laboratory monitoring is performed according to indicated schedule for medication

TREATMENT OF HD IN THE U.S.

I. Clinical Spectrum of HD

The clinical features of HD cover a wide range, from a single hypopigmented skin macule to very generalized disease. Wide differences are seen in the pathological features, immunological status, treatment required, and types of complications that develop. For treatment purposes, the NHDP uses the WHO two-group classification, into which the Ridley-Jopling five-group classification is incorporated.

II. Treatment

Treatment of HD involves more than simply prescribing medication. Many patients fear they will become severely disabled and will spread the disease to their families. They also fear they will suffer socially if others find out. Good health education at the time of diagnosis and during the course of treatment will make it more likely that the patient will have a better outcome. Thus, an important part of the management of HD is providing accurate information to patients and families regarding the expected course and prognosis of the disease.

A. Paucibacillary (PB)-Dapsone 100mg daily plus rifampin 600 mg. daily for one year and then stop treatment
   1. Indeterminate (I) HD is the earliest stage of disease, and consists of one or two vague hypopigmented macules, slightly dry in texture, with anhidrosis, and generally, no M.leprae in the lesion. Over half of these cases resolve without treatment, others progress eventually into one of the other forms of HD.
   2. Tuberculoid (TT) is limited disease with few, well-defined hypopigmented skin lesions which have marked sensory loss. Loss of hair in the lesion is common and there if often central healing. Without treatment, lesions may enlarge slowly, or self-heal. M.leprae are few or hard to find, but peripheral nerve involvement common, leading to severe disabilities if nerve damage occurs.

B. Multibacillary (MB)-Dapsone 100mg daily plus rifampin 600 mg daily plus clofazimine 50 mg daily for two years, and then stop treatment.

1. Borderline (BT, BB, BL) disease has features of both the tuberculoid and lepromatous types of HD. Skin lesions occur in small and large sizes and may be hypo- or hyper-pigmented. These lesions may or may not be anesthetic.
2. Lepromatous (LL) type disease is characterized by lesions which are numerous, small, and symmetrically distributed. They may be hypo- or hyper-pigmented. The skin, nerves, bones, eyes, and nasal area are most often affected; however, all organs may become involved. There may be elongated ear lobes with partial or complete loss of the eyebrows. There may be anhidrosis of some parts of the body.

C. Common Side-effects of HD medications
1. Dapsone
   a. Contraindications-prior allergy to dapsone G6PD deficiency, breast-feeding
   b. Side effects-hemolysis
2. Rifampin
   a. Contraindications-prior allergy to rifampin
   b. Side effects-abnormal liver function, thrombocytopenia, drug interactions with oral contraceptives and anticoagulants, reddish discoloration of urine, stools, saliva, tears, and sweat
3. Clofazimine
   a. Contraindications-none indicated
   b. Side effects-discoloration of skin, diarrhea, abdominal pain, less commonly, bowel obstruction

4. In the event of intolerance or drug toxicity to the usual drugs, the NHDP may be contacted for recommendations regarding alternative regimens.

D. Performance Standard
1. Biopsy is done to determine type of HD for proper treatment to be initiated
2. Baseline laboratory studies are performed before initiating treatment
3. Drug allergy is ruled out through patient's medical history
4. Patients presenting with complaints of side-effects from HD medications are assessed by nurse and referred to HD clinic physician for treatment
5. Patient education includes medications, dosages, and side effects of medications, required visit for laboratory monitoring

E. Follow-Up after Completion of Treatment

Clinical examinations and biopsies or skin smears
Should be done at the following intervals:
1. Paucibacillary (PB)
   a. Every six months for two years

b. Annually for three years

2. Multibacillary (MB)
   a. Every six months for two years
   b. Annually for eight years

F. Performance Standard
   1. Follow-up for Paucibacillary disease is done according to schedule in E.1. above
   2. Multibacillary disease is followed up per schedule in E.2. above

REACTIONS IN HD

Although M.leprae is almost non-toxic, some patients develop acute hypersensitivity "reactions" to the organism. These are known as "lepra reactions". Reports of the frequency of reactions indicate that 25% to 50% of all HD patients will have a reaction sometime during the course of the disease. There are no predictors of which patients will develop reaction, other than patients with tuberculoid disease do not have reactive episodes. Reactions are also less frequent in patients taking clofazimine. There are two types of reaction, Reversal Reaction or Type I Reaction, and Erythema Nodosum Leprosum, or ENL, which is Type II Reaction. Most patients with reaction can be treated as outpatients. For guidance on management of reaction, call the NHDP at 1-800-642-2477.

I. Symptoms of Reaction
   A. Neuritis-enlarged or tender peripheral nerves; changes in sensation or strength
   B. Muscle weakness
   C. Tender, painful, erythematous nodules which may ulcerate
   D. Development of new lesions
   E. Malaise
   F. Fever-low-grade to moderate
   G. Red, painful eyes
   H. Orchitis in patients with multibacillary disease
   I. Edema of hands and feet

II. Treatment of Reactions

Reactions are a major cause of nerve damage, so the focus of management should be on the prevention of nerve damage. Damage to the nerves is caused by the tissue response within the nerves to intraneural M. leprae and is similar to the process seen in the skin. In untreated HD, without reaction, nerve damage is more insidious while during reactions nerves may be damaged more rapidly. Skin reactions and acute neuritis often occur together. Antibacterial treatment should be continued at full dosage.

Patients with mild reaction may be treated symptomatically. Those with moderate to severe reaction patients may require steroids, thalidomide, or

clofazimine. Patients with severe reaction, especially those with evidence of nerve damage, require treatment with corticosteroids.

A. Treatment with steroids
   1. Contraindications
      a. Inadequately treated infection
      b. Situation where medically supervised stoppage of medication is not possible
      c. Prolonged usage without close medical supervision
   2. Side effects
      a. Weight gain or potassium loss
      b. New infection or exposure to an infectious person
      c. Poor response to some immunizations
      d. Interaction with laboratory and medical care results such as blood sugar and TB skin tests
      e. Withdrawal effects

B. Thalidomide is very effective in controlling ENL, and is the drug of first choice if not contraindicated. This drug is very teratogenic and causes severe birth defects if taken by women during pregnancy. In the U.S., thalidomide is investigational in the NHDP for the treatment of reaction in HD. It can be given to women of childbearing age only if they have been surgically sterilized or if hospitalized at the NHDP in Baton Rouge, using birth control measures. Male patients taking this medication must use prophylactics during sexual intercourse.

   In some facilities, thalidomide is available using the Celgene STEPS program; however, it is very expensive.
   1. Contraindications
      a. Pregnancy
      b. No unauthorized person may take this medication
   2. Side effects
      a. Fetal developmental defects
      b. Constipation
      c. Drowsiness
      d. Dizziness

C. Clofazimine can be given in a dose of 300mg daily for four-six weeks, reduced to 200 mg daily for several months, and then reduced to 100mg daily. The addition of clofazimine at these doses will usually make it possible to reduce the dose of steroids required, but not eliminate them entirely. Clofazimine is not quick acting and it may take six weeks or more for the full effect on the reaction to be noted. Patients receiving larger doses of clofazimine will have more severe skin pigmentation and more frequent gastro-intestinal side effects.

   When the patient has required no steroids for approximately three months, the dosage of clofazimine can be reduced to 50mg daily. If the clofazimine is not required for antibacterial treatment, it can be

discontinued when no steroids have been required for an additional three months.

For consultation on the treatment of reaction, call the NHDP at 1-800-642-2477. For more information on reaction, see "Resources".

D. Performance Standard
   1. Medical assessment and treatment should be done on patients with symptoms of reaction in order to prevent permanent nerve injury.
   2. Patient knows symptoms of reaction to report to healthcare provider
   3. Patient knows side-effects of medication prescribed for reaction which must be reported for evaluation
   4. Patients on thalidomide have documented consent forms indicating procedure and protocol has been explained.

CONTACT SURVEILLANCE

In the U.S., a contact is identified as a person living in the same household with a new patient, up to three years, at the time of diagnosis. A contact exam which includes:

I. Contact examination
   A. Exam of the entire skin
   B. Nerve function assessment of the peripheral nerves, focusing primarily on the eyes, hands, and feet (See Appendix).
   C. The contact exam should also include patient education on the disease, and what symptoms a contact should report to the health care provider.

   An individual suspected of having HD may be referred to one of the Outpatient HD Clinics or to the NHDP by physicians or healthcare Agencies. These persons will be provided with the services required to rule out the diagnosis of HD, as described above.

II. Follow-Up of Contacts
   A. For contacts of a paucibacillary case, no follow-up is necessary, as long as the patient has been educated about the symptoms of HD.
   B. In contacts of a multibacillary case, exams should be done annually for five years, including patient education about the disease and its symptoms
   C. The NHDP does not recommend chemoprophylaxis with dapsone or any other drug for contacts of patients.
   D. Performance Standard
      1. Exam of contacts or suspects includes all aspects described under a, "Contact Exam", above.
      2. Follow-up exams are done according to the schedule above.
      3. Patient education provided to contacts is documented.

CONSULTANT SERVICES

I. Due to the multi-faceted aspects of this disease, patients may need referral to the following ancillary medical services for complications. Not all consultant services will be needed in every case and some will be indicated only rarely. Consultation with NHDP staff is also available by calling 1-800-642-2477.
   - A. Physical Therapy
   - B. Occupational Therapy
   - C. Podiatry
   - D. Orthotics
   - E. Orthopedics
   - F. Ophthalmology
   - G. ENT

II. Performance Standard

Patients with complications from HD will be referred to consultants as necessary.

REHABILITATION SERVICES

I. Disability prevention is promoted by the visual inspection of the eyes, hands, and feet of the patient at each encounter. Should the hands or feet require further evaluation, a hand or foot screen and palpation of the nerves should be done (See Appendix).

II. Services include:
   - A. Eye-Ophthalmological services are needed for persons with paucibacillary HD who may have incomplete palpebral closure or loss of corneal sensation. Patients with multibacillary disease may have infiltration of the anterior part of the eye with HD bacilli. Patients with eye complaints should be referred to the ophthalmologist.
   - B. Occupational and Physical Therapy-These services include hand and foot screens, reporting changes in sensory and motor function to the physician, teaching prevention of disability, providing wound care, fabricating splints and casts, recommending assistive devices, rehabilitation tendon transfers and other orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.
   - C. Preoperative casting, wound care, and post-operative rehabilitation provided by Ambulatory Care Program therapists decreases the length of stay required for those patients referred to the NHDP.

III. Performance Standard
   - A. Hand and Foot Screens and Peripheral Nerve Exam are performed on all patients according to schedule or as necessary
   - B. Patients with positive findings receive medical assessment and referral to consultant services as necessary.

PROFESSIONAL AND PATIENT EDUCATION

I. Patient Education

Appropriate treatment of a stigmatizing disease like HD involves more than merely prescribing medications. Many patients fear they will become severely disabled and will infect their families. They also fear social isolation if others become aware of their diagnosis. Awareness of these patient concerns at the time of diagnosis and during the course of treatment will more likely ensure patient compliance with treatment and achieve its objective, which is the prevention of deformity and disability. Printed and audiovisual materials are available from the NHDP.

A. Physical assessment, HD monitors, hand and foot screens all offer opportunities for patients to learn about HD and how it affects them.

B. Incorporate disability prevention into all patient education

II. Professional Education

A. Asian and Hispanic minority populations represent the largest number of patients diagnosed in the U.S. These communities should be included in the community outreach educational programs by the healthcare provider

B. Encourage medical and nursing students to participate in or visit the HD clinic

C. Provide the local medical association with information about HD clinic services for publication in their newsletter; invite local media to include information about HD clinic services and HD as part of community service news

III. Standard of Care

A. Patient education is documented on all patient encounters, including hand and foot screens.

B. Education is geared to disability prevention as elimination deformity and associated stigma

C. Program evaluation will reflect professional educational activities such as student rotations, lectures at other healthcare facilities, media involvement in education of community about HD

INPATIENT CARE

Medical staff at the NHDP may authorize an inpatient admission on a case-by-case basis.

RESOURCES

I. Resources available from the NHDP for HD are:

A. Consultation on treatment and management guidelines

B. Medications for HD: dapsone, rifampin, clofazimine

C. Processing and reading of skin smears

D. Processing biopsies for histopathology

E. Hand and foot screen forms
F. Professional and patient audiovisual and printed educational materials
G. HD and Foot Seminars for Physicians, Nurses, Occupational Therapists, Physical Therapists, Orthotists, and Podiatrists
H. NHDP Website-www.bphc.hrsa.gov/nhdp

Information regarding these services and materials is available from the NHDP, 1770 Physicians Park Drive, Baton Rouge, LA, 70816, Phone 800-642-2477; Fax 225-756-3760

II. Other Resources

A. American Leprosy Missions
1 ALM Way
Greenville, SC 29601
Phone: 800-543-3131

B. IDEA (International Association for Integration, Dignity, And Economic Advancement)
U.S. Headquarters
P.O. Box 651
32 Fall Street-Suite A
Seneca Falls, NY 13148
Phone: 315-568-5838 Fax: 315-568-5891
E-mail:alaw@idealeprosydignity.org

Reporting Requirements

I. A Hansen's Disease Surveillance Form on all newly-diagnosed patients as soon as the diagnosis is confirmed.
II. Initiation of HD Therapy reporting form
III. The contractor shall submit monthly an electronic report on diskette generated with the use of Microsoft Access or compatible database with the invoice containing the following information:

A. Name of all patients, birth date, social security number, and address
B. Number of clinic visits, if any, for each patient during the reporting period
C. HD medications each patient is receiving and start date
D. Type and number of consultant visits (OT, PT, etc.) per patient during the reporting period
E. Hard copy of all hand and foot screens performed during the reporting period

IV. Annual Report:

A. Report of all deceased patients, including birth date, social security number, date and cause of death, if known
B. Follow-up HD Treatment reporting
C. Thalidomide report

D. A brief description of the annual independent audit. If deficiencies were identified, note them and how they were corrected and addressed.

V. Other reports and information to be determined by the project officer as part of an ongoing evaluation program to determine the effectiveness of the care provided under this contract.

APPENDIX

FORMS AND PROCEDURES

HANSEN'S DISEASE TREATMENT REPORTING FORM
NEW PATIENT

Date _____

Patient's Name: _____ DOB: __/__/__ of Report: _____

Newly Diagnosed: ___ Date of Diagnosis: _____ Previously Treated: _____

Date of Initial Therapy: _____ Summarize Previous Treatment:_____

_____

Ever Admitted to NHDP: Yes _____ No _____ NHDP # _____

Clinical Findings:

1. Briefly describe skin lesions: _____
2. Motor Loss: Yes _____ No _____. If Yes, Describe: _____
3. Sensory Loss: Yes _____ No _____. If Yes, Describe: _____
4. Enlarged or Tender Nerves: Yes _____ No _____. If Yes, Describe: _____

_____

5. Reaction at the time of diagnosis: ENL _____ REVERSAL REACTION _____
   OTHER _____ NONE _____. If Reaction present Describe: _____
   Treatment: _____
6. Briefly describe any other HD related findings such as Madarosis, Xerosis, Eye Findings, Etc.: _____

_____

7. Clinical Diagnosis: _____
8. Skin Smears: Sites 1. _____ BI _____ 2. _____ BI _____ 3. _____ BI _____
   4. _____ BI _____ 5. _____ BI _____ 6. _____ BI _____
9. Biopsy: Yes _____ No _____. If Yes, Date: _____ Diagnosis: _____

_____

10. Describe Treatment to be initiated: _____

_____

_____

Signature City State

(If additional space is needed, write on the back or add another page.)

Rev. KW 3/00

HANSEN'S DISEASE TREATMENT REPORTING FORM
FOLLOW-UP

Date _____

Patient's Name: _____ DOB: __/__/__ of Report: _____

Admitted to NHDP during last year: Yes _____ No _____ NHDP # _____

1. Clinical Diagnosis: _____
2. Skin Smears this year: None _____ Date, if obtained: _____
3. Biopsies: None _____. Date, if done this year: _____

   Diagnosis: _____ Average BI: _____
4. Any clinical changes during the last Year? Yes _____ No _____

   If yes, describe: _____

_____

Compliance: Dapsone spot check on urine during last years. # + / # - _____

Patients on Clofazimine: Any signs of Clofazimine pigmentation? Yes _____ No _____

Medication since last report: If therapy completed, Date _____

For each drug indicate doses dispensed/required during 12 months since last report.

Dapsone _____/_____ Clofazimine _____/_____

Rifampin _____/_____ Others _____/_____

5. Complications: Reversal reaction in last year: Yes _____ No _____ ENL in last year: Yes _____ No _____ If yes, summarize condition and treatment: _____

_____

Does reaction still require therapy? Yes _____ No _____.

6. Neural, motor or sensory changes: Improvement _____ No change _____ Deterioration _____ Describe any improvement or deterioration and any specific treatment _____

_____

Does problem still require treatment? Yes _____ No _____.

7. Other complications: Yes _____ No _____. If yes, describe: _____

_____

8. Drug toxicity? Yes _____ No _____. If yes, describe: _____

_____

Is the patient still receiving this drug? Yes _____ No _____

9. Other comments: _____

_____

_____
Signature City State

(If additional space is needed, write on the back or add another page.)

Rev. KW 3/00

Hansen's Disease Monitors

The Hansen's disease (HD) monitors are a system of assessment which includes a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. These procedures can be used to teach patients about prevention of complications.

1. **Visual Inspection**

   a. Eyes
      1. Examine the eyes for inflammation
      2. Check the size, shape, and reaction to light of the pupils
      3. Ask the patient to close their eyes and check for incomplete closure

   b. Hands
      1. Inspect the palms and dorsum of the hands for dry skin
      2. Muscle atrophy and injuries which may be the result of sensory loss and motor nerve involvement

   c. Feet
      1. Inspect for dry skin, erythema, calluses, and injuries
      2. Check socks and shoewear for signs of drainage from ulcers or injuries

2. **Motor Function Assessment**

   These assessments should be done with the application of resistance by the examiner, otherwise early signs of weakness may be missed. (See attachment)

3. **Shoewear Assessment for Insensitive Feet**

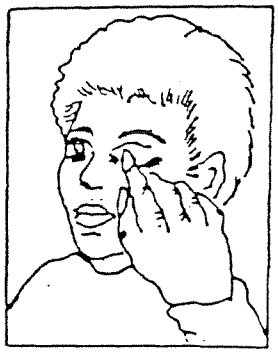
   a. Extra-depth shoes with removable insoles
   b. Rounded or square toe box
   c. Leather upper
   d. A half-inch length beyond longest toe
   e. No seams at the toe
   f. Soft wedge sole

A patient with a positive eye exam should be evaluated by an ophthalmologist; hand and foot problems need follow-up with a hand or foot screen and referred as necessary.

HANSEN'S DISEASE MONITORS

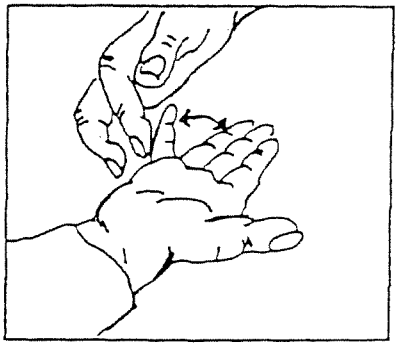
FACIAL NERVE

Have patient close eyes while applying gentle resistance to eyelids.



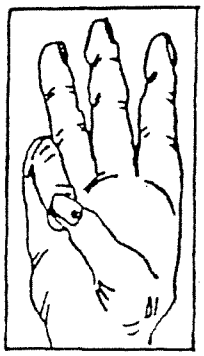
ULNAR NERVE

Have patient abduct little finger against resistance applied by examiner.



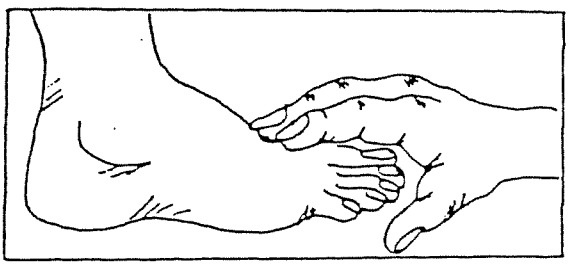
MEDIAN & ULNAR NERVES

Have patient approximate little finger and thumb with hand in prone position.



PERONEAL NERVE

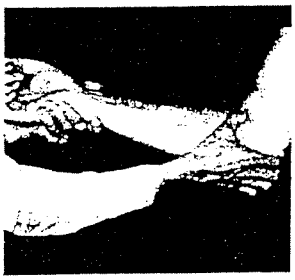
Ask the patient to bring foot up. Apply resistance when foot is up. There will be weakness or paralysis when patient is unable to resist the downward movement that is applied to the foot.



These assessments are to be done with application of resistance by examiner; otherwise early signs of weakness may be missed. A patient with a positive eye exam should be evaluated by an ophthalmologist. Positive hand or foot assessments can be further evaluated through a hand or foot screen and referred.

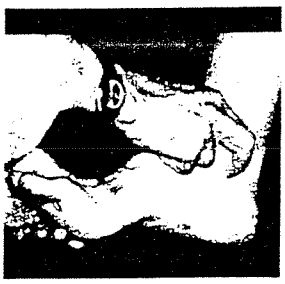
PERIPHERAL NERVES ASSESSMENT

Greater auricular-with the patient's head turned to one side, palpate the nerve as it stretches across the sternomastoid muscle.



Ulnar-palpate above the ulnar groove.

Radial cutaneous-palpate at the lateral border of the radius proximal to the wrist joint.



Posterior tibial-posteriorly and inferiorally to the medial malleolus.

Common peroneal-palpate the popliteal fossa just medial to the biceps femoris tendon, and around the neck of the fibula.

SKIN BIOPSY

A proper site is the single most important factor in the skin biopsy to be evaluated for leprosy. The pathologist will be unable to make a definite diagnosis if bacilli cannot be demonstrated by means of the biopsy. A general rule is that the biopsy should be taken entirely within the lesion, preferably from the active margin if there is one; this is especially important in the non-lepromatous forms of leprosy. There is no necessity to include any normal tissue in the biopsy. Where several different lesions exist, it is best to biopsy all lesions. When no definite lesion can be found, the site for biopsy should be guided by information from skin scrapings and clinical findings such as decreased sensation and decreased sweating.

The skin biopsy should be made with a biopsy punch or by surgical excision. In all instances, the biopsy should be deep enough to include subcutaneous fat; this depth of biopsy is very important, for often the most prominently involved nerves will be found in the upper portion of the subcutaneous tissue. A 4 mm or larger biopsy punch should be used; a 2 or 3 mm punch biopsy can be made on the face, if necessary. Surgical excision is made 1 cm by 3 mm, with a cold knife; removal of specimens by cautery is to be entirely avoided. A proper fixative should be employed for specimen fixation and transfer; 10% neutral buffered formalin is used routinely. At least five volumes of fixative per volume of tissue should be used.

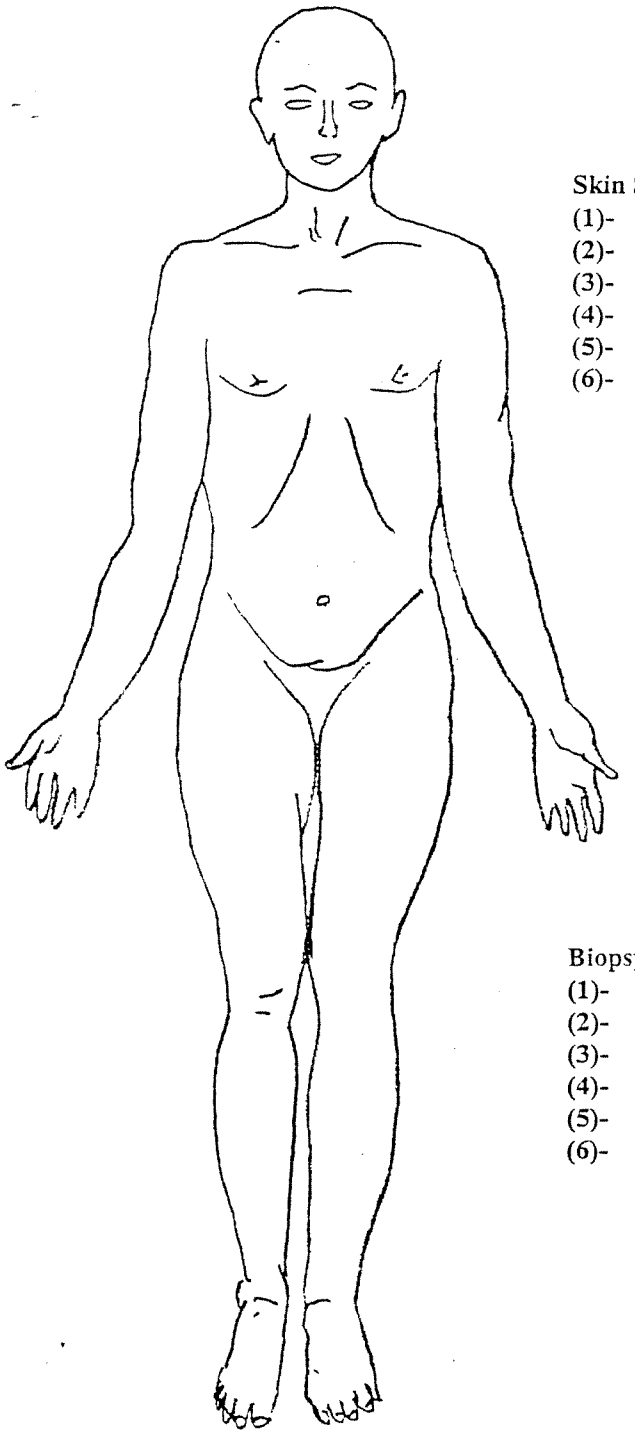
NERVE BIOPSY

Adequate clinical information should always be submitted with the specimen. The site of the biopsy should always be stated. The attached diagram is helpful. Relevant information includes: number of lesions, changes in sensation, previous diagnosis and present clinical impressions, patient name, date of birth, sex, race, and social security number if available.

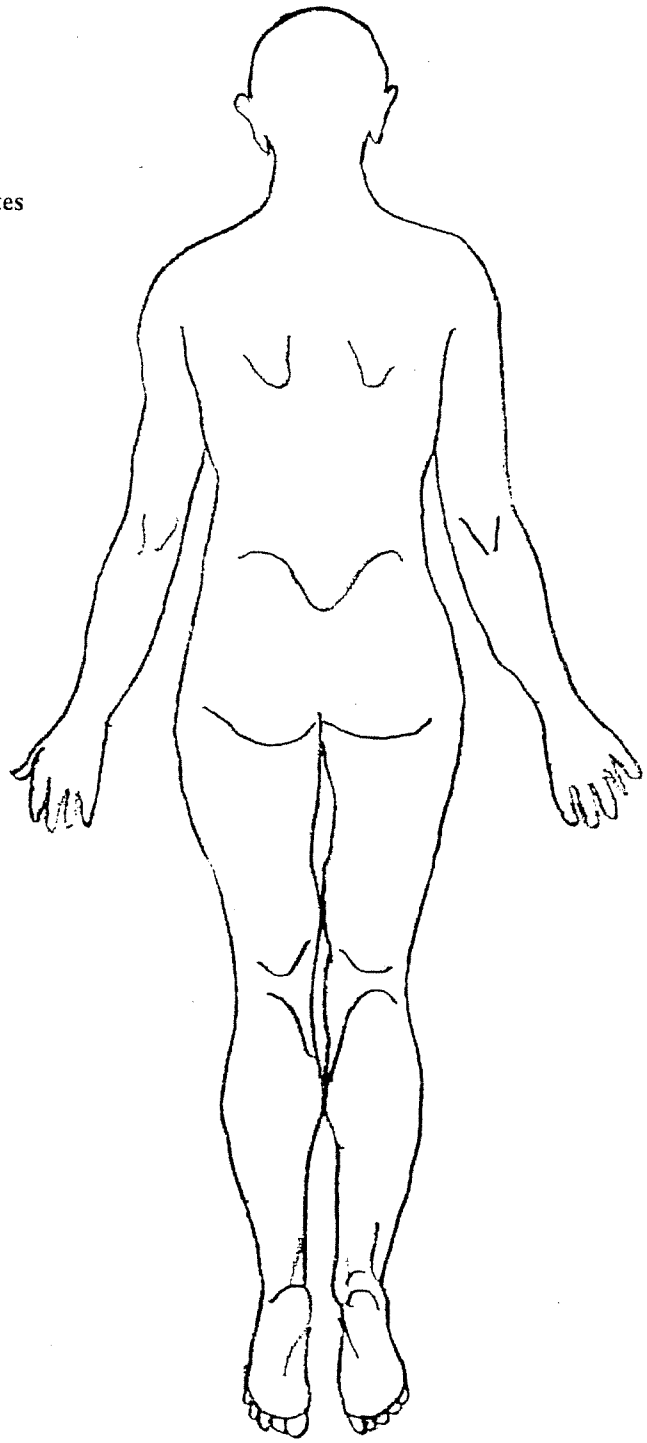
For histopathological consultation, at no charge, mail specimens in 10% neutral buffered formalin to:

National Hansen's Disease Programs
Attention: Clinical Laboratory
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816

NATIONAL HANSEN'S DISEASE PROGRAMS	SKIN SMEAR / BIOPSY CHART	Date:
Patient's Name (Last, First, Middle)		HD ID No.
Date of Birth:	Social Security No.	Date of Dx.



Skin Smear Sites
(1)-
(2)-
(3)-
(4)-
(5)-
(6)-



Biopsy Sites
(1)-
(2)-
(3)-
(4)-
(5)-
(6)-

Private Physician's:

Name: _____
Address: _____
_____
Phone: _____

SKIN SMEARS FOR ACID-FAST BACILLI

PURPOSE:

The skin smear is a valuable, cost-effective tool in the routine management of the Hansen's disease patient. The smear is a means of estimating the number of acid-fast bacteria present, reported as the bacterial index (BI), and is important in determining the type and severity of disease as well as assessing the response to treatment.

GENERAL:

1. Initial skin smears are usually taken from 6 "routine sites" (both earlobes, elbows, and knees) as well as several typical lesions from the patient.

   Repeat smears are obtained from 3 to 4 of the most active sites previously tested to evaluate progress.

2. The time interval between repeat smears is determined by the physician but in general, annual smears are adequate for monitoring response to treatment and during the follow-up period to detect any evidence of relapse.

3. They may be sent in protective mailers to:

   National Hansen's Disease Programs
   Attention: Clinical Laboratory - Skin Smears
   1770 Physicians Park Drive
   Baton Rouge, Louisiana 70816
   Phone: (225) 756-3733

STAINING OF SKIN SMEARS

1. Dry the slide with smear at room temperature. **DO NOT HEAT FIX.**
2. Place slides on a staining rack and flood with 10% formalin for 15 minutes for fixation.
3. Rinse with tap water.
4. Flood slides with Ziehl-Neelsen carbol-fuchsin for twenty minutes. (Always filter stain before each use.)
5. Rinse with tap water.
6. Decolorize with 2% acid alcohol for 1 minute.
7. Rinse slides thoroughly with tap water.
8. Counterstain with alkaline methylene blue for 30 seconds to 1 minute.
9. Rinse with tap water and air dry.

NOTE: Positive and negative control slides must be used each day for quality control purposes.

Z-N Carbol Fuchsin Stain:

Basic fuchsin.....1.0 gm.
Phenol crystals.....5.0 gms.
95% ethanol.....10.0 mls.
Water, to make.....100.0 mls.

Acid alcohol:

Conc. HCl.....2.0 mls.
95% ethanol.....98.0 mls.

Alkaline Methylene Blue:

KOH (10%).....10.0 mls.
Methylene blue..... 0.35 gms.
95% ethanol..... 16.0 mls.
Water to make..... 100.0 mls.

MICROSCOPIC EXAMINATION OF SKIN SMEARS:

The stained smears are examined with a quality microscope using the oil immersion objective (x100) to determine the total number of bacilli. The same individual should read all smears for the purpose of consistency. The smear will have similar numbers of bacilli throughout, however, four separate quadrants of the smear are examined and averaged to establish the Bacterial Index (BI).

REPORTING THE BACTERIAL INDEX (BI):

The results are reported on a 0 to 6+ semi-logarithmic scale using a descriptive phrase or numerical code. This is an indicator of the total bacillary load of the patient. It falls about 1 point per year during effective treatment as dead bacilli undergo lysis and are absorbed.

Very Numerous	(+6)	-	over 1000 bacilli per oil immersion field.
Numerous	(+5)	-	100 to 1000 bacilli per oil immersion field.
Moderate	(+4)	-	10 to 100 bacilli per oil immersion field.
Few	(+3)	-	1 to 10 bacilli per oil immersion field.
Very few	(+2)	-	1 to 10 bacilli per 10 fields.
Rare	(+1)	-	1 to 10 bacilli per 100 fields.
None found	(NF)	-	No AFB seen on entire site.

PROCEDURE FOR OBTAINING SMEARS

1. Universal precautions should be observed in obtaining skin smears.

2. All microscopic slides on which skin smears are made should be precleaned in 70% alcohol, acetone, or alcohol-acetone to remove amorphous debris. The slides are wiped dry with a clean hand towel. Blades that are used in smear taking are likewise cleaned.

3. The skin is cleansed with 70% alcohol and air-dried or wiped dry with cotton. (Zepharin tends to make the skin too slippery and is not recommended.)

4. A fold of skin is made relatively avascular by pinching or mild clamping. If the skin cannot be grasped by pinching, it can be compressed. A surgeon's glove may aid in grasping.

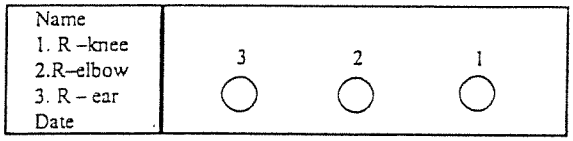
5. Local anesthesia is generally unnecessary. (If there is not adequate decrease in sensation, obtain local anesthesia with 1% Xylocaine, or Ethyl Chloride spray can be carefully applied.) The compression of the skin by pinching aids in the anesthesia.

6. An incision 3-5 mm long and 2-3 mm deep is made with an alcohol cleansed single-edged razor blade or a scalpel with a #15 Bard-Parker blade may also be used. **The blade or scapel should be used for only one site and then discarded.** Mild pressure to maintain relative avascularity is continuously applied to the area until an adequate smear has been obtained.

7. A small amount of blood does not interfere with the reading, but large amounts should be avoided and can usually be controlled by the amount of pressure of the pinch. If excessive bleeding occurs, it can be wiped away with a cotton swab.

8. After the incision is made, and before the blade is withdrawn, the inner surface of the wound is scraped with the blade held at a right angle to the incision. Upon scraping, tissue fluid and dermal tissue are obtained.

9. The material is transferred to the cleaned microscope slide. A moderately thick smear, with a visible uniform opacity is made. The smear is made in a circular manner on the slide, **no larger than a pencil eraser (5-7 mm)** in diameter, beginning peripherally and ending in the center, leaving a central "button" (2-4 mm) which can be easily focused upon with the microscope. Slides should be properly labeled as shown in the sample diagram for 3 routine sites.



10. Slides should be air-dried and **NEVER** heat fixed.

11. A Band-Aid is generally sufficient to protect the smear site.

12. A single technician takes all smears to provide for more uniform and consistent results.

13. The smears may be sent to the National Hansen's Disease Programs for reading.

14. A chart to diagram sites of the skin smears is attached for convenience.

STANDARDS FOR PERFORMANCE OF HAND SCREEN

The hand screen is intended to record the baseline and risk assessment of patients requiring acute care, or receiving health education, and it helps identify patients in need of treatment to prevent progressive nerve damage (decrease in sensory and muscle function). The majority of patients may not have sensory or muscle involvement of the hands or will have long-standing involvement that is not changing.

Long standing sensory and muscle loss that is unchanging does not need treatment of the nerve, however, the patient may benefit from deformity prevention techniques (splitting/education/adaptive devices).

The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measures levels of cutaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

WHEN TO PERFORM THE SCREEN

- A baseline hand screen is performed on all new patients.
- Annual screens are performed on all patients during therapy and as follows:

  Paucibacillary patients - for 5 years post therapy
  Multibacillary patients - for 10 years post therapy

- Screens may be performed more often if the patient complains of muscle weakness, a decrease in sensation or in hand function since the last evaluation

- Monthly hand screens are completed on patients in reaction who have evidence of nerve involvement or more frequently if necessary during treatment for reaction

PATIENTS WITH NERVE CHANGES:

Patients whose sensory and muscle function has deteriorated over the last 6-12 months are experiencing reaction in the nerves; these are considered "acute" nerves.

Patients with "acute" nerves need immediate attention in order to prevent progression in nerve involvement, and examination by the physician for treatment of the nerve with cortico-steriods or other anti-inflammatory agents.

Referral to an occupational therapist may be warranted for patient education in reducing stress on the acute nerve, protection of the nerve, or temporary immobilization.

HAND SCREEN FORM

PATIENT DATA:

Use middle initial or middle name if available.

HD ID Number - Use patient's social security number.

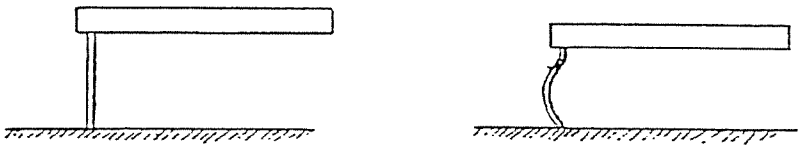
SECTION I. SENSORY TEST:

A. Perform the test with the patient's eyes closed or averted.

B. Select the sites to be tested as indicated on the Hand Screen form.

C. Use Filament #1, the lightest, first. If equates to normal sensation (0.05 gram).

D. Apply the filament slowly to bending (just before bending to the heaviest), hold 1.5 seconds, remove slowly.



E. Apply the filament three times (slowly) in succession and record if the patient feels any of the three applications.

F. If the first filament is not felt, proceed to the next heavier filament, repeating the process until a filament is felt.

G. Record the number of the filament first felt in the appropriate blank, next to the appropriate number. If no filament is felt, put a zero in the blank to indicate the test was completed for that site, but the patient did not respond.

H. Do not allow the filament to slide across the skin.

I. Ask the patient to reply "yes" when the filament is felt.

J. Apply the filament along the margin of and NOT on an ulcer site, callous or scar.

SECTION II. SKIN INSPECTION:

Use initials indicated on form to mark hand map and for lesions and observations made of the condition of the patient's hands.

SECTION III. MUSCLE TESTING:

Results of muscle testing are graded as strong, weak, or paralyzed.

Strong - Normal ROM and full resistance

Weak - Reduced ROM with reduced or no resistance

Paralyzed - No contraction palpable.

1. Abduction of index finger (ulnar).
   Index finger should be abducted with some slight flexion in the knuckle joint, with all other joints straight. Apply resistance at the base of the index finger. Thumb of supporting hand can palpate for possible muscle contraction.

2. Abduction of little finger (ulnar).
   Ask patient to move little finger out and slightly up, palm side up, keeping all the joints of the finger straight. Apply resistance at the base of the little finger. Fingers of your supporting hand will be able to palpate for possible muscle contraction.

3. Abduction of the thumb (median).
   Move thumb away from palm of hand at right angles to the plane of the palm of the hand. Resistance is applied at the base of the thumb, pushing it in to the index finger.

4. Opposition of the thumb (median).
   Have patient make ring with thumb and little finger, try to push thumb out.

5. Wrist extension (radial).
   Ask the patient to make a fist, and try to push the wrist down on the radial side. If weakness is present, patient may not be able to resist or wrist may deviate to unaffected side.

SECTION IV. PERIPHERAL NERVE RISK:

Weakness or paralysis is usually not present wherever normal sensation or sweating is found. Loss of sensation and weakness may occur at the same time as sensory loss or sometimes months or years later.

Peripheral nerve involvement of short duration is more apt to be responsive to treatment. Acute nerve involvement may be successfully minimized or reversed by treatment with corticosteroids, anti-inflammatory agents, immobilization, wrapping to keep it warm, or possibly surgery (nerve transfer).

Classification is graded on a scale of 1 to 4.

Risk Category 1:

A patient in this category may need to be followed for the possibility of further problems.

Risk Category 2:

Tender nerve on stretch or compression, with the ulnar nerve in the area of the olecranon process in the elbow. May be tender on flexion of arm or if pressure applied to area. To palpate for an enlarged nerve, use the four fingers of one hand and gently roll the nerve under them. A normal nerve is slightly thick or may not be palpable at all. A hard, sclerosed nerve is abnormal.

Risk Category 3:

Sensory change in the last 12 months.

Risk Category 4:

Muscle change in the last 12 months.

Section V: DEFORMITY RISK:

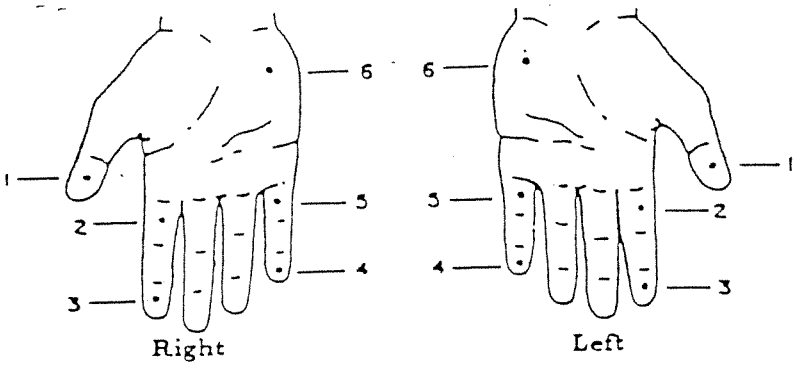
This is classified from a range of 1 to 5, which lists types of disability which may be present in a patient.

Hand Screen forms should be sent to:

National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge, LA 70816

HD PHYSICIAN PROGRAM	HAND SCREEN RECORD	Date:
Patient's Name(Last, First, Middle)_____		HD ID No:
Patient's File No:	Medications:	Date of Disease Onset:	Initial_____ F/U_____

Section I. SENSORY TESTING: Use first filament (A) at site indicated. (If no response, use next heavier to determine level of loss.)

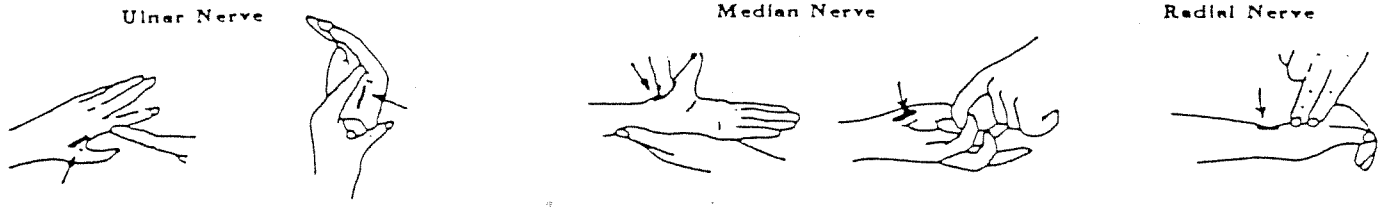


Filament	Force, gms	Interpretation
A (Green)	0.05	(normal)
B (Blue)	0.20	(residual texture)
C (Purple)	2.00	(residual protective sensation)
D (Red)	4.00	(loss of protective sensation)
E (Orange)	300.00	(residual deep pressure)

Section II. SKIN INSPECTION: Draw and Label: W - Wound, C - Callus, S - Swelling, R - Redness, D - Dryness T - Temperature, M - Missing, J - Contracture, O - Other

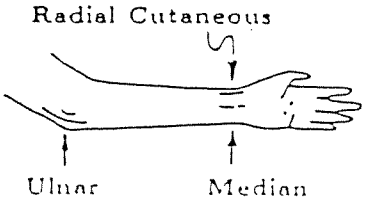
Section III. MUSCLE TESTING: (Mark S = Strong, W = Weak, P = Paralysis)

Index Finger Abduction (FDI)	Little Finger MP Joint Flex. (L)	Thumb Abduction Out of Palm (APB)	Thumb to Little Finger (OP)	Radial Wrist Extension (ECR)
Ulnar Nerve		Median Nerve		Radial Nerve
R__ L__	R__ L__	R__ L__	R__ L__	R__ L__



Section IV. PERIPHERAL NERVE RISK: (Mark U, M, or UM)

1. Enlarged or swollen nerve	R__ L__
2. Tender/painful on stretch or compression	R__ L__
3. Sensory change in the last 12 months	R__ L__
4. Muscle change in the last 12 months	R__ L__
High Risk:	Yes__ No__



Section V. DEFORMITY RISK: (Check if present)

1. Loss of Protective Sensation	R__ L__
2. Clawed but Mobile Hand	R__ L__
3. Fingertip Absorption (check Mild__ Severe__)	R__ L__
4. Injuries (open wounds, blisters, etc.)	R__ L__
5. Contracted or Stiff Joints	R__ L__
High Risk:	Yes__ No__

Has there been a change in the hand since the last exam? Yes__ No__

Examined by: _____

The Regional Hansen's Disease Program
Carville, Louisiana
Rev. 01/09/90

STANDARDS FOR THE PERFORMANCE OF THE FOOT SCREEN

The initial foot screen is intended to record the baseline status of patient subjective data and clinical signs and symptoms of neurological impairment. The foot screen evaluates history or presence of plantar ulceration, strength of specific muscles, plantar foot sensation, and deformities which can place the foot at risk of injury. After the initial evaluation, screens are performed annually to monitor or pick up any undetected changes by the patient and are indicated more often if the patient perceives any change in sensory, motor or functional status. The screen is a tool to bring up any treatment issues such as wound, callus, and toenail care, footwear and orthotic needs.

The Screen is also used to place the patient in a Risk Category. The foot screen assessment section or risk category serves as a guideline for routine foot checks. This check up is for monitoring and trimming plantar callus and toenails and for checking on appropriateness of patient footwear and orthotics.

The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder and is designed to deliver a 10 gram force when properly applied. Our research has shown that a patient who can feel the 10 gram filament in the selected sites will not develop ulcers.

Routine follow up is based on the objective data and is suggested as follows:

- Category 0 - No Loss of Protective Sensation (LOPS) - annual foot screen only
- Category 1 - LOPS but no deformity - check up every six months
- Category 2 - LOPS and deformity - check up every three months
- Category 3 - LOPS and history of ulceration monthly check ups
- Category 4 - Charcot foot - monthly check ups

WHEN TO PERFORM THE SCREEN

- A baseline foot screen is performed on all new patients.
- Annual foot screens are performed on all patients during therapy as follows:

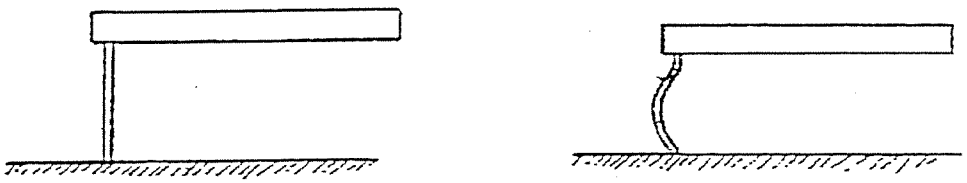
  Paucibacillary patients for 5 years post therapy
  Multibacillary patients for 10 years post therapy

- Screens may be performed more often if the patient perceives a change in sensory, motor, or functional status

FOOT SCREEN ENCOUNTER FORM

Instructions for sensory testing on the foot:

1. Use the 10 gram filament provided to test sensation.
2. Select the sites to be tested based on the Foot Screening Form.
3. Apply the filament perpendicular to the skin's surface. (See diagram A)
4. The approach, skin contact and departure of the filament should be approximately 1 ½ seconds duration.
5. Apply sufficient force to cause the filament to bend. (See diagram B)



6. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
7. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.
8. Ask the patient to respond "yes" when the filament is felt.
9. Apply the filament along the perimeter of and NOT on an ulcer site, callous, scar or necrotic tissue.
10. Foot screens are performed annually. If the patient has symptoms of neurities, e.g., burning on the soles of the feet, pain in the lower extremities, or is on treatment for neuritis, the foot screen should be done more frequently to monitor progress or to refer to the clinician.
11. A copy of the Foot Screen must be sent to the NHDP.

REGIONAL HD CENTER	FOOT SCREEN RECORD	Date:
Patient's Name(Last, First, Middle)_____		HD ID No:
Patient's File No:	Social Security No:	Initial_____ F/U_____

Fill in the following blanks with an **R**, **L**, or **B** to indicate positive findings on the right, left or both feet.

Has there been a change in the foot since last evaluation? Yes__ No__ N/A__

Is there a foot ulcer now or history of foot ulcer? Yes__ No__

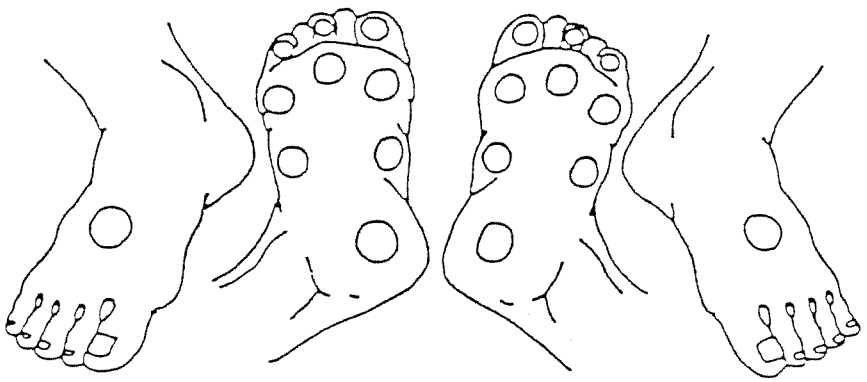
Does the foot have an abnormal shape? Yes__ No__

Is there weakness in the ankle or foot? Yes__ No__

Are the nails thick, too long or ingrown? Yes__ No__

Label: Sensory Level with a "+" in the circled areas of the foot if the patient can feel the 10 gram (5.07 Semmes-Weinstein) nylon filament and "–" if he/she can not feel the 10 gram filament.

RIGHT



LEFT

Draw in and Label: Callus ▨, Pre-ulcer ▩, Ulcer ■ (Note width/depth in cm.)
Skin Condition with R - Redness, S - Swelling, W - Warmth, D - Dryness, M - Maceration

Does the patient use footwear appropriate for his/her category? Yes__ No__

RISK CATEGORY:

__ 0 No loss of protective sensation.

__ 1 Loss of protective sensation (no weakness, deformity, callus, pre-ulcer or Hx. ulceration.)

__ 2 Loss of protective sensation with weakness, deformity, pre-ulcer or callus but no Hx. ulceration within last 2 years.

__ 3 History of plantar ulceration within last 2 years.

__ 4 Charcot foot

Date of Next Evaluation: (Guidelines)				
	Category 0	One Year _____	Category 2	Six Months _____
	Category 1	One Year _____	Category 3	One to Three Months _____

Rev. 07/19/89

WHO GRADING OF DISABILITIES
HANDS AND FEET

Grade 0: No anesthesia, visible deformity, or damage

Grade 1: Anesthesia present, but no visible deformity or damage

Grade 2: Visible deformity or damage present

Each hand and foot should be assessed and graded separately. "Damage" in this context includes ulceration, shortening, disorganization, stiffness, or loss of part or all of the hand or foot. If any disability found in the patient is due to causes other than leprosy, this fact should be noted.

CONSENT TO PARTICIPATE IN RESEARCH PROTOCOL

THALIDOMIDE IN THE LONG-TERM CONTROL OF ERYTHEMA NODOSUM LEPROSUM, PHASE III

THALIDOMIDE CONSENT FORM A

(To be used in men, and in women who are sterilized or not of childbearing age)

Thalidomide is a drug, which has been shown by many doctors to be extremely effective in the treatment of ENL (fever with "tubercules," etc.); however, its use for this condition is experimental and if you desire to receive the drug you need to be informed of the risks involved. The only currently available alternative treatment for this condition, which is likely to be of equal efficacy, is corticosteroids (e.g., Prednisone). Like any medicine, Thalidomide may occasionally produce undesirable side effects in some people. We want you to know about these before giving you the drug, and your doctor will be happy to answer any questions you have.

1. You will feel sleepy when you first take it and therefore should avoid driving, working around dangerous machinery or placing your self in any position where you should be alert and wide awake. This drowsiness produced by the drug will probably gradually decrease the longer you take the medicine and as the number of tablets you take each day is reduced.

2. Occasionally some patients taking Thalidomide have difficulty with constipation or swelling of the feet and lower legs. Your doctor will be able to advise you further if these problems occur.

3. Rarely people have developed decreased sensation as a result of taking Thalidomide. This would usually not occur with less than a year of treatment, and we have not seen this in any leprosy patient as yet. You should know that it may occur, however, and may not disappear when your medicine is stopped. Report to your doctor at once should any new sensory loss develop while you are on Thalidomide.

4. Thalidomide may produce serious birth defects in infants born to mothers who take it during pregnancy. For this reason it can be given to women of childbearing potential only if special precautions to help them avoid pregnancy are taken. Males taking Thalidomide must wear condoms and avoid unprotected intercourse.

5. About one patient in ten may develop some abnormalities of his blood while taking Thalidomide. To date these have never proven to be serious, and usually the medicine can be continued in spite of them. The possibility exists that a serious abnormality of the blood could develop, however, so you should keep all the appointments with your doctor for checkups or see him if any new illness or unusual symptom develops.

6. As with any medicine, new side effects may appear the longer the drug is used. Thus, regular follow-up appointments with your doctor are essential and you must keep these appointments.

7. This drug, if given to you, is for your use only and you must assume full responsibility to prevent anyone else from taking it. The drug should be stored in a locked cabinet.

8. Thalidomide has been detected in semen. Although the clinical implication is unclear, it is recommended that all males receiving the drug should use a condom during sexual intercourse.

I have read the foregoing. I understand the importance and the potential value to me and others of my taking Thalidomide as an investigational drug. I understand that there are risks of undesirable side effects, both known and unknown. The known risks have been explained to me. I recognize that there are unknown risks in taking Thalidomide as there are in taking any drug. I accept the risks and desire to take the drug.

In the event of physical injury resulting from taking Thalidomide, full medical treatment is available, but financial compensation for wages lost because of injury or illness is not available. Full information concerning this can be obtained from the office of the Director, Capt. Charles D. Stanley, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3774. The contact person for answers to questions about Thalidomide and your rights, and whom to contact in the event of an injury related to the intake of Thalidomide, is M. Patricia Joyce, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3709 or (800) 642-2477.

Before giving my consent by signing this form I have been sufficiently informed of the reason I am being asked to take Thalidomide, the investigational nature of Thalidomide, of the methods, means and duration of administration of the drug, of the inconveniences, hazards, or adverse effects that may result from use of this drug.

I further understand that my taking of Thalidomide is voluntary and that I may discontinue taking it whenever I choose and without loss of benefits to which I am otherwise entitled. Such discontinuance will not jeopardize my future treatment. I understand that if I have any questions regarding this study or this form they will be answered so that I satisfactorily and completely understand. The individual to contact in this regard is M. Patricia Joyce, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3709 or (800) 642-2477. If I choose to withdraw from the study, no new information about me will be collected for study purposes unless the information concerns an adverse event (bad effect) related to the study. If such an adverse event occurs, Dr. Joyce may need to review and copy my entire medical record. All information already collected for study purposes and any new information about an adverse event will be disclosed to the Dr. Joyce and to the US Food and Drug Administration. If I decide to withdraw, I should contact Dr. Joyce at the above address and telephone number to let her know I am withdrawing from this study.

Patient Initials _____

I acknowledge my responsibility to keep my appointments with my doctors, to report to them immediately the earliest suggestion of something amiss and to protect others from unauthorized taking of the drug.

I authorize release of my personal information from this study to those agencies designated by the principle investigator and/or the granting agency. This information is considered protected health information (PHI) and is individually identifiable, consisting of health and medical information with my personal identification attached, such as medical records, laboratory test results, photographs, and hospital or clinic bills if any, The Federal Privacy Rule requires that I give my authorization before PHI can be disclosed to a third party, such as any study sponsor or used for research. My consent to participate in this research study is separate from consent to allow disclosure and use of PHI. If I agree to participate in this study and authorize the disclosure of my PHI, the information may be reviewed by Dr. Joyce (as study sponsor) and representatives from the Tulane Health Science Center and from the US Food and Drug Administration, to review and copy any of the previously stated medical records. The Privacy rule does not prevent any third party from disclosing my PHI to someone else. My authorization to disclose or use my PHI does not have an expiration date, but I may revoke my authorization for the disclosure and use of my PHI at any time.

I have read this consent form and voluntarily agree to participate in this research study. My signature also authorizes the use and disclosure of the identifiable health information (PHI) as described in this consent form. This consent is effective from 2-20-03 to 2-20-04.

_____ _____

Patient/Date Witness/Date

I am unable to read English, but this consent form has been read and explained to me by:

_____Name of reader

_____ _____

Patient/Date Witness/Date

_____

(Signature of Reader)

Consentimiento para Participar en Protocolo de Investigación

Talidomida Para El Control de Eritema Nodoso Leproso, Fase III

Forma A de Consentimiento para Talidomida
1. Para pacientes masculinos
2. Para pacientes femeninos sin posibilidad de embarazo, por razón de esterilización, o por edad

La Talidomida es una medicina que ha sido demostrada por muchos médicos de extrema eficacia en el tratamiento de la reacción leprosa, o "ENL" (fiebre con tubérculos). Sin embargo, su uso para esta condición es experimental. Si usted desea tomar esta medicina, necesita informarse acerca de los riesgos al tomarla. La única medicina alternativa disponible en la actualidad para esta condición es la Prednisona, que es igualmente efectiva. Como cualquier medicina, la Talidomida puede ocasionar efectos secundarios no deseados en algunas personas. Queremos que esté informado acerca de estos efectos antes de comenzar el tratamiento y su médico le puede dar respuestas a sus preguntas.

1. Sentirá sueño cuando empiece a ingerir la Talidomida y por lo tanto no debe manejar su auto, maquinaria pesada, o ponerse en situaciones que requieran estar alerta y despierto. Esta sensación de mareo producida por la medicina probablemente disminuya gradualmente a medida que vaya ingiriendo el medicamento y cuando le bajen la dosis que ingiera diariamente.

2. Ocasionalmente algunos pacientes que estén ingiriendo Talidomida sufrirán de estreñimiento o hinchazón de pies y de las piernas. Su médico le orientará si esto ocurriese.

3. Rara vez algunas personas han desarrollado sensación disminuida con este tratamiento. Usualmente esto no ocurre en la persona bajo tratamiento por menos de un año, y este efecto no se ha visto en un paciente con Hansen. Usted debe estar enterado que este efecto puede ocurrir y es posible que no desaparezca una vez termine el tratamiento. Necesita comunicarle a su médico si desarrolla nuevas áreas de sensación disminuida mientras esté ingiriendo Talidomida.

4. La Talidomida puede producir serios defectos congénitos en infantes nacidos de madres que estén ingiriendo el medicamento durante su etapa de embarazo. Por esta razón se le puede dar a estas pacientes si toman precauciones especiales para evitar un embarazo. Pacientes masculinos deben usar preservativos durante la relación sexual y evitar tener relaciones sexuales sin protección.

5. Uno de cada diez pacientes puede desarrollar algunas anormalidades en su sangre mientras estén ingiriendo esta medicina. Hasta ahora no se ha probado que sea serio y usualmente se puede continuar el tratamiento a pesar de esto. Existe la posibilidad de poder desarrollar serias anormalidades en la sangre; sin embargo,

para prevenir esto debe asistir a todas las citas con su médico o verlo si se desarrolla alguna nueva dolencia o síntoma poco usual.

6. Como cualquier medicina, nuevos efectos secundarios pueden aparecer mientras más tiempo sea usado el medicamento. Por eso las citas médicas con regularidad son esenciales.

7. Esta medicina es recetada sólo para su uso personal y usted asume toda la responsabilidad de evitar que otras personas la ingieran. Se debe guardar en un botiquín seguro.

8. La Talidomida se puede encontrar en el semen. Aunque las implicaciones clinicas no están determinadas, es recomendable que todos los pacientes masculinos que estén ingiriendo esta medicina utilizen preservativos durante las relaciones sexuales.

He leído lo anterior. Entiendo la importancia y el valor potencial para mí y para otros que estén ingiriendo esta nueva medicina experimental. Entiendo que hay riesgos de efectos secundarios no deseados, tanto conocidos como desconocidos. Los riesgos conocidos me han sido explicados. Reconozco que hay riesgos desconocidos al ingerir Talidomida así como los hay al ingerir cualquier otro medicamento. Acepto los riesgos y deseo tomar la medicina.

Entiendo que en el evento de daño fisico que resulte por ingerir Talidomida, recibiré tratamiento médico completo, pero no recibiré compensación financiera por pérdida de sueldo por consecuencia de daño fisico o enfermedad. Entiendo que puedo obtener información completa relacionada a este tratamiento a través de la oficina del Director, CAPT Charles D. Stanley, del Programa Nacional de Hansen, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3773 o al 1-800-642-2477.

Para obtener respuestas a preguntas o preocupaciones relacionadas a este tratamiento y sus derechos, y en caso de daño causado por la Talidomida, me puedo comunicar con la doctora M. Patricia Joyce, Rama Clínica, Programa Nacional de Hansen, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3709 o al 1-800-642-2477.

Antes de firmar este consentimiento, me han brindado información adecuada sobre la razón para recomendar esta medicina, su naturaleza experimental, los métodos, modos y duración de la administración de la Talidomida, de los inconvenientes, riesgos y efectos adversos que pueden resultar al ingerir esta medicina.

Entiendo que el uso de la Talidomida es voluntario y que puedo descontinuar el tratamiento en cualquier momento sin pérdida de beneficios o derechos. Mi tratamiento en el futuro no se verá afectado al descontinuarla. Entiendo que si tengo preguntas acerca de este consentimiento, me serán contestadas de manera satisfactoria. Para más información al respecto, me puedo comunicar con la doctora M. Patricia Joyce, Rama

Clínica, Programa Nacional de Hansen, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3709 o al 1-800-642-2477. Si decido descontinuar mi participación de esta investigación, no se recopilará información personal para propósitos investigativos a menos que dicha información esté relacionada con algún efecto adverso surgido durante el tratamiento. De así ocurrir, la doctora Joyce tendrá que revisar y reproducir mi expediente médico completo. Toda información ya recopilada para propósitos investigativos y alguna información nueva basada en un efecto adverso, será suministrada a la doctora Joyce y a la Administración de Drogas y Alimentos de Estados Unidos. Si decido no participar en la investigación, debo comunicarme con la doctora Joyce a la dirección y número telefónico arriba indicado para notificarle mi decisión.

Reconozco mi responsabilidad de mantener todas las citas con mis médicos, de notificarles inmediatamente cualquier malestar, y de prevenir el uso de esta medicina por otras personas que no están autorizadas a ingerir la misma.

Autorizo a que se divulgue la información de este estudio a aquellas agencias designadas por el investigador principal y a quienes más la soliciten. Esta información está considerada información de salud confidencial e identificada individualmente, constando de información personal médica y de salud, incluyendo expedientes médicos, resultados de exámenes de laboratorio, fotografías y facturas de hospital o clínicas, si alguna. La Ley Federal de Información Confidencial requiere mi autorización para la divulgación de mi información confidencial a otras agencias o para otros estudios investigativos. Mi consentimiento para participar en este estudio investigativo está separado de mi autorización para la divulgación de mi información confidencial y de salud.

Si decido participar en esta investigación y autorizo a que se divulgue mi información confidencial y de salud, esta información puede ser revisada y reproducida por la doctora Joyce, como patrocinadora de esta investigación, representantes del Centro de Salud y Ciencias Tulane, y la Administración de Drogas y Alimentos de Estados Unidos. La Ley Federal de Información Confidencial no impide que estas agencias aquí nombradas puedan distribuir dicha información a otras agencias. Mi autorización para la divulgación o uso de mi información confidencial y de salud no tiene fecha de expiración, pero yo puedo revocar mi autorización para la divulgación o uso de esta información en cualquier momento.

He leído y entiendo esta información y firmo mi consentimiento voluntariamente. Mi firma también autoriza el uso de mi información confidencial y de salud según explicado en esta forma de consentimiento. Este consentimiento es válido de _____ **a** _____.

_____ _____

Paciente/Fecha Testigo/Fecha

Yo no puedo leer, pero este consentimiento se me ha leído y explicado y entiendo su contenido.

_____ _____

Paciente/Fecha Testigo/Fecha

_____

(Firma de Lector)

CONSENT TO PARTICIPATE IN RESEARCH PROTOCOL

THALIDOMIDE IN THE LONG-TERM CONTROL OF ERYTHEMA NODOSUM LEPROSUM, PHASE III

THALIDOMIDE CONSENT FORM B

(To be used in women of childbearing age who have not been sterilized.)

Thalidomide is a drug, which has been shown by many doctors to be extremely effective in the treatment of ENL (fever with "tubercules," etc.); however, its use for this condition is experimental and if you desire to receive the drug you need to be informed of the risks involved. The only currently available alternative treatment for this condition, which is likely to be of equal efficacy, is corticosteroids (e.g., Prednisone). Like any medicine, Thalidomide may occasionally produce undesirable side effects in some people. We want you to know about these before giving you the drug, and your doctor will be happy to answer any questions you have.

1. You will feel sleepy when you first take it and therefore should avoid driving, working around dangerous machinery or placing your self in any position where you should be alert and wide awake. This drowsiness produced by the drug will probably gradually decrease the longer you take the medicine and as the number of tablets you take each day is reduced.

2. Occasionally some patients taking Thalidomide have difficulty with constipation or swelling of the feet and lower legs. Your doctor will be able to advise you further if these problems occur.

3. Rarely people have developed decreased sensation as a result of taking Thalidomide. This would usually not occur with less than a year of treatment, and we have not seen this in any leprosy patient as yet. You should know that it may occur, however, and may not disappear when your medicine is stopped. Report to your doctor at once should any new sensory loss develop while you are on Thalidomide.

4. Thalidomide may produce serious birth defects in infants born to mothers who take it during pregnancy. For this reason it can be given to women of childbearing potential only if special precautions to help them avoid pregnancy are taken. Males taking Thalidomide must wear condoms and avoid unprotected intercourse.

5. About one patient in ten may develop some abnormalities of his blood while taking Thalidomide. To date these have never proven to be serious, and usually the medicine can be continued in spite of them. The possibility exists that a serious abnormality of the blood could develop, however, so you should keep all the appointments with your doctor for checkups or see him if any new illness or unusual symptom develops.

6. As with any medicine, new side effects may appear the longer the drug is used. Thus, regular follow-up appointments with your doctor are essential and you must keep these appointments.

Patient Initials _____

7. This drug, if given to you, is for your use only and you must assume full responsibility to prevent anyone else from taking it. The drug should be stored in a locked cabinet.

have read the foregoing. I understand the importance and the potential value to me and others of ny taking Thalidomide as an investigational drug. I understand that there are risks of undesirable side effects, both known and unknown. The known risks have been explained to me. I recognize that :here are unknown risks in taking Thalidomide as there are in taking any drug. I accept the risks and desire to take the drug.

understand that thalidomide may produce serious birth defects in any child I conceive while taking it. therefore agree to (1) take birth control pills regularly as prescribed, (2) stop the thalidomide and report to my physician at once if I do not have a menstrual period for over 30 days, (3) have a pregnancy test performed weekly, and remain in the infirmary at the National Hansen's Disease Programs, Baton Rouge, Louisiana, while taking the drug.

understand that in spite of the above precautions the possibility exists that I could become pregnant while on thalidomide. The desirability of having a therapeutic abortion, should this occur, has been explained to me. Whether I choose to have an abortion or not will remain my own decision, but I will not hold the manufacturer or supplier of the drug, any of my physicians, or the U. S. government, or ts physicians, responsible for the defects resulting in any children I may conceive or deliver while on :halidomide.

n the event of physical injury resulting from taking Thalidomide, full medical treatment is available, out that financial compensation for wages lost because of injury or illness is not available. Full nformation concerning this can be obtained from the office of the Director, Capt. Charles D. Stanley, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3774. The contact person for answers to questions about Thalidomide and your rights, and whom to contact in the event of an injury related to the intake of Thalidomide, is M. Patricia Joyce, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3709 or (800) 642-2477.

Before giving my consent by signing this form I have been sufficiently informed of the reason I am being asked to take Thalidomide, the investigational nature of Thalidomide, of the methods, means and duration of administration of the drug, of the inconveniences, hazards, or adverse effects that nay result from use of this drug.

further understand that my taking of Thalidomide is voluntary and that I may discontinue taking it whenever I choose and without loss of benefits to which I am otherwise entitled. Such discontinuance will not jeopardize my future treatment. I understand that if I have any questions regarding this study or this form they will be answered so that I satisfactorily ad completely understand. The individual to contact in this regard is M. Patricia Joyce, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3709 or (800) 642-2477. If I choose to withdraw from the study, no new information about me will be collected for study purposes unless the information concerns an adverse event (bad effect) related to he study. If such an adverse event occurs, Dr. Joyce may need to review and copy my entire nedical record. All information already collected for study purposes and any new information about an adverse event will be disclosed to the Dr. Joyce and to the US Food and Drug Administration. If I

Patient Initials _____

decide to withdraw, I should contact Dr. Joyce at the above address and telephone number to let her know I am withdrawing from this study.

acknowledge my responsibility to keep my appointments with my doctors, to report to them mmediately the earliest suggestion of something amiss and to protect others from unauthorized aking of the drug.

authorize release of my personal information from this study to those agencies designated by the principle investigator and/or the granting agency. This information is considered protected health nformation (PHI) and is individually identifiable, consisting of health and medical information with my personal identification attached, such as medical records, laboratory test results, photographs, and hospital or clinic bills if any, The Federal Privacy Rule requires that I give my authorization before PHI can be disclosed to a third party, such as any study sponsor or used for research. My consent to participate in this research study is separate from consent to allow disclosure and use of PHI. If I agree to participate in this study and authorize the disclosure of my PHI, the information may be reviewed by Dr. Joyce (as study sponsor) and representatives from the Tulane Health Science Center and from the US Food and Drug Administration, to review and copy any of the previously stated medical records. The Privacy rule does not prevent any third party from disclosing my PHI to someone else. My authorization to disclose or use my PHI does not have an expiration date, but I may revoke my authorization for the disclosure and use of my PHI at any time.

- As an alternative, women of childbearing age not wishing to be hospitalized in the Infirmary of the National Hansen's Disease Program may obtain Thalidomide from a private physician through commercial sources by enrolling in the Celgene S.T.E.P.S. Program.

have read this consent form and voluntarily agree to participate in this research study. My signature also authorizes the use and disclosure of the identifiable health information (PHI) as described in this consent form. This consent is effective from 2-20-03 to 2-20-04.

_____ _____

Patient/Date Witness/Date

am unable to read English, but this consent form has been read and explained to me by:

_____ Name of reader

_____ _____

Patient/Date Witness/Date

_____

(Signature of Reader)

Consentimiento para Participar en Protocolo de Investigación

Talidomida Para El Control de Eritema Nodoso Leproso, Fase III

Forma B de Consentimiento para Talidomida
(Para mujeres de edad parturienta que no han sido esterilizadas)

La Talidomida es una medicina que ha sido demostrada por muchos médicos de extrema eficacia en el tratamiento de la reacción leprosa, o "ENL" (fiebre con tubérculos). Sin embargo, su uso para esta condición es experimental. Si usted desea tomar esta medicina, necesita informarse acerca de los riesgos al tomarla. La única medicina alternativa disponible en la actualidad para esta condición es la Prednisona, que es igualmente efectiva. Como cualquier medicina, la Talidomida puede ocasionar efectos secundarios no deseados en algunas personas. Queremos que esté informado acerca de estos efectos antes de comenzar el tratamiento y su médico le puede dar respuestas a sus preguntas.

1. Sentirá sueño cuando empiece a ingerir la Talidomida y por lo tanto no debe manejar su auto, maquinaria pesada, o ponerse en situaciones que requieran estar alerta y despierto. Esta sensación de mareo producida por la medicina probablemente disminuya gradualmente a medida que vaya ingiriendo el medicamento y cuando le bajen la dosis que ingiera diariamente.

2. Ocasionalmente algunos pacientes que estén ingiriendo Talidomida sufrirán de estreñimiento o hinchazón de pies y de las piernas. Su médico le orientará si esto ocurriese.

3. Rara vez algunas personas han desarrollado sensación disminuida con este tratamiento. Usualmente esto no ocurre en la persona bajo tratamiento por menos de un año, y este efecto no se ha visto en un paciente con Hansen. Usted debe estar enterado que este efecto puede ocurrir y es posible que no desaparezca una vez termine el tratamiento. Necesita comunicarle a su médico si desarrolla nuevas áreas de sensación disminuida mientras esté ingiriendo Talidomida.

4. La Talidomida puede producir serios defectos congénitos en infantes nacidos de madres que estén ingiriendo el medicamento durante su etapa de embarazo. Por esta razón se le puede dar a estas pacientes si toman precauciones especiales para evitar un embarazo. Pacientes masculinos deben usar preservativos durante la relación sexual y evitar tener relaciones sexuales sin protección.

5. Uno de cada diez pacientes puede desarrollar algunas anormalidades en su sangre mientras estén ingiriendo esta medicina. Hasta ahora no se ha probado que sea serio y usualmente se puede continuar el tratamiento a pesar de esto. Existe la posibilidad de poder desarrollar serias anormalidades en la sangre, sin embargo, para prevenir esto debe asistir a todas las citas con su médico o verlo si se desarrolla alguna nueva dolencia o síntoma poco usual.

6. Como cualquier medicina, nuevos efectos secundarios pueden aparecer mientras más tiempo sea usado el medicamento. Por eso las citas médicas con regularidad son esenciales.

7. Esta medicina es recetada sólo para su uso personal y usted asume toda la responsabilidad de evitar que otras personas la ingieran. Se debe guardar en un botiquín seguro.

8. La Talidomida se puede encontrar en el semen. Aunque las implicaciones clínicas no están determinadas, es recomendable que todos los pacientes masculinos que estén ingiriendo esta medicina utilizen preservativos durante las relaciones sexuales.

He leído lo anterior. Entiendo la importancia y el valor potencial para mí y para otros que estén ingiriendo esta nueva medicina experimental. Entiendo que hay riesgos de efectos secundarios no deseados, tanto conocidos como desconocidos. Los riesgos conocidos me han sido explicados. Reconozco que hay riesgos desconocidos al ingerir Talidomida así como los hay al ingerir cualquier otro medicamento. Acepto los riesgos y deseo tomar la medicina.

Entiendo que la Talidomida puede producir serios defectos congénitos en cualquier niño que conciba mientras la ingiero. Por lo tanto estoy de acuerdo en:

A. Ingerir pastillas contraceptivas regularmente según prescrito.

B. Detener el tratamiento de Talidomida y notificar a mi médico si me falta una menstruación por más de 30 días.

C. Hacerme una prueba de embarazo semanalmente.

D. Permanecer recluída en el Hospital del Programa Nacional de Hansen.

Entiendo que aún con las precauciones anteriores existe la posibilidad de quedar embarazada mientras ingiero la Talidomida. Se me ha explicado que lo ideal en este caso es un aborto terapeútico. El seleccionar o no el aborto es una decisión mía, pero no haré responsible por los defectos que resulten en cualquier niño que yo conciba o tenga mientras ingiera Talidomida al manufacturero o suplidor de la medicina, al médico que ordena el tratamiento, ni al Servicio de Salud Pública de Estados Unidos.

Entiendo que en el evento de daño físico que resulte por ingerir Talidomida, recibiré tratamiento médico completo, pero no recibiré compensación financiera por pérdida de sueldo por consecuencia de daño físico o enfermedad.

Entiendo que puedo obtener información completa relacionada a este tratamiento a través de la oficina del Director, CAPT Charles D. Stanley, del Programa Nacional de Hansen,

1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3773 o al 1-800-642-2477.

Para obtener respuestas a preguntas o preocupaciones relacionadas a este tratamiento y sus derechos, y en caso de daño causado por la Talidomida, me puedo comunicar con la doctora M. Patricia Joyce, Rama Clínica, Programa Nacional de Hansen, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3709 o al 1-800-642-2477.

Antes de firmar este consentimiento, me han brindado información adecuada sobre la razón para recomendar esta medicina, su naturaleza experimental, los métodos, modos y duración de la administración de la Talidomida, de los inconvenientes, riesgos y efectos adversos que pueden resultar al ingerir esta medicina.

Entiendo que el uso de la Talidomida es voluntario y que puedo descontinuar el tratamiento en cualquier momento sin pérdida de beneficios o derechos. Mi tratamiento en el futuro no se verá afectado al descontinuarla. Entiendo que si tengo preguntas acerca de este consentimiento, me serán contestadas de manera satisfactoria. Para más información al respecto, me puedo comunicar con la doctora M. Patricia Joyce, Rama Clínica, Programa Nacional de Hansen, 1770 Physicians Park Drive, Baton Rouge, Louisiana 70816, teléfonos (225) 756-3709 o al 1-800-642-2477. Si decido descontinuar mi participación de esta investigación, no se recopilará información personal para propósitos investigativos a menos que dicha información esté relacionada con algún efecto adverso surgido durante el tratamiento. De así ocurrir, la doctora Joyce tendrá que revisar y reproducir mi expediente médico completo. Toda información ya recopilada para propósitos investigativos y alguna información nueva basada en un efecto adverso, será suministrada a la doctora Joyce y a la Administración de Drogas y Alimentos de Estados Unidos. Si decido no participar en la investigación, debo comunicarme con la doctora Joyce a la dirección y número telefónico arriba indicado para notificarle mi decisión.

Reconozco mi responsabilidad de mantener todas las citas con mis médicos, de notificarles inmediatamente cualquier malestar, y de prevenir el uso de esta medicina por otras personas que no están autorizadas a ingerir la misma.

Autorizo a que se divulgue la información de este estudio a aquellas agencias designadas por el investigador principal y a quienes más la soliciten. Esta información está considerada información de salud confidencial e identificada individualmente, constando de información personal médica y de salud, incluyendo expedientes médicos, resultados de exámenes de laboratorio, fotografías y facturas de hospital o clínicas, si alguna. La Ley Federal de Información Confidencial requiere mi autorización para la divulgación de mi información confidencial a otras agencias o para otros estudios investigativos. Mi consentimiento para participar en este estudio investigativo está separado de mi autorización para la divulgación de mi información confidencial y de salud.

Si decido participar en esta investigación y autorizo a que se divulgue mi información confidencial y de salud, esta información puede ser revisada y reproducida por la doctora Joyce, como patrocinadora de esta investigación, representantes del Centro de Salud y Ciencias Tulane, y la Administración de Drogas y Alimentos de Estados Unidos. La Ley Federal de Información Confidencial no impide que estas agencias aquí nombradas puedan distribuir dicha información a otras agencias. Mi autorización para la divulgación o uso de mi información confidencial y de salud no tiene fecha de expiración, pero yo puedo revocar mi autorización para la divulgación o uso de esta información en cualquier momento.

Para la mujer de edad parturienta que no desea permanecer recluída en el hospital del Programa Nacional de Hansen en Baton Rouge, Louisiana, puede obtener la Talidomida de su médico privado a través de la participación en el Programa S.T.E.P.S. de la compañia farmacéutica Celgene y la farmacia que auspicia ese programa en su localidad.

He leído y entiendo esta información y firmo mi consentimiento voluntariamente. Mi firma también autoriza el uso de mi información confidencial y de salud según explicado en esta forma de consentimiento. Este consentimiento es válido de _____ **a** _____.

_____ _____

Paciente/Fecha Testigo/Fecha

Yo no puedo leer, pero este consentimiento se me ha leído y explicado y entiendo su contenido.

_____ _____

Paciente/Fecha Testigo/Fecha

_____

(Firma de Lector)

He leído lo anterior y lo entiendo y estoy de acuerdo en no hacer responsible a los manufactureros o suplidores de la medicina o al Servicio de Salud Pública de Estados Unidos o sus médicos por los defectos que resulten en cualquier niño que mi esposa o hija (tache aquellas que no apliquen) puedan concebir o tener mientras esté recibiendo tratamiento de Talidomida.

_____ _____

Esposo de la Paciente o Guardián Legal/Fecha Testigo/Fecha

THALIDOMIDE PATIENT REPORT FORM

1. Date of report _____

2. Patient's name (Last, First, Middle I.) _____

3. a) Date of birth _____ b) Place of birth _____

4. Race: _____

5. Sex: Male _____ Female _____

   If female: Post menopausal? Yes _____ No _____. If No – what measures have been taken to prevent pregnancy (hysterectomy, tubal ligation, etc.).

6. Patient's disease classification (circle one):

   a) lepromatous leprosy (LL)
   b) borderline-lepromatous (BL)
   c) borderline (BB)
   d) indeterminate
   e) borderline-tuberculoid (BT)
   f) tuberculoid (TT)

7. a) Date of diagnosis _____ b) Date ENL began _____

8. Date Thalidomide started _____.

9. Mean dose of Thalidomide taken during the year _____.

10. Side effects due to Thalidomide only. _____

    _____ None (other than sedation) _____

11. Laboratory abnormalities due to Thalidomide only. _____

    _____ None noted _____

12. Other leprosy related drugs taken during the past year only:

Drug	Date Started	Dose
Dapsone (DDS, Aviosulfone)	_____	_____
Clofazimine (B663, Lamprene)	_____	_____
Rifampin (Rimactane®, Rifadin®)	_____	_____
Other _____	_____	_____

13. Response to Thalidomide therapy (circle one):
    a) Good (complete control of ENL)
    b) Fair (partial control of ENL)
    c) Poor (no response)
    d) Unknown
    e) Lost to follow-up

14. Was written informed consent obtained from this patient? Yes _____ No _____
    Is it available for inspection if required? Yes _____ No _____

15. Is patient still on therapy? Yes _____ (Dose _____) No _____(Date Discont._____)

16. Previous therapy for ENL

Drug	Dose	Duration of Therapy
Corticosteroids	_____	_____
Clofazimine (B663, Lamprene)	_____	_____
Other _____	_____	_____

17. Laboratory data before therapy. Normal _____ Abnormal _____ Not done _____
    List of any abnormalities _____
    BI on skin scraping or biopsy(s) before start of therapy _____

    _____

18. Has the patient ever been admitted to Carville? Yes _____ No _____
    If yes, what dates? _____ Carville # (if known) _____

Clinical Investigator: _____
(Signature)

Instructions for Completing the Hansen's Disease *(Leprosy)* Surveillance Form

The Hansen's Disease or Leprosy Surveillance Form *(LSF)* is the document used to report leprosy cases to the U.S. National Hansen's Disease Registry. These data are used for epidemiological, clinical, and basic research studies throughout the National Hansen's Disease Program *(NHDP)*, and are the official source for information on leprosy cases in the U.S.

The information requested on the LSF is used by many clinicians and researchers, and collection of all information is highly desirable. However, the fields that are **boldfaced** on the form and in the instructions below are considered to be the minimal information needed to register a patient. Failure to provide this information will result in the form being returned which creates additional work and may cause delays in obtaining program services for the patient.

1. **Reporting State:** Use the abbreviation of the state from which the report is being sent. This is usually the state of the clinician's office and not necessarily the patient's resident state.
2. **Date of Report:** This is date of the initial LSF completion. If patient was previously reported and has relapsed, write the word "RELAPSE" next to the date.
3. Social Security Number: self-explanatory.
4. **Patient Name:** Self-explanatory.
5. **Present Address:** Please include the county and zip code which are used to geographically cluster patients.
6. **Place of Birth:** Include state and county, if born in the U.S., or the country, if foreign born.
7. **Date of Birth/Sex:** Self-explanatory.
8. **Race/Ethnicity:** This information should be voluntarily provided by the patient. If the patient refuses or indicates a race/ethnicity category not listed, check the "Not Specified" box.
9. **Date Entered the U.S.:** For patients who have immigrated to the U.S., provide the month and year of entry.
10. Date of Onset of Symptoms: This information is usually the patient's recollection of when classic leprosy symptoms *(rash, nodule formation, paresthesia, decreased peripheral sensation, etc.)* were first noticed.
11. **Date Leprosy First Diagnosed:** Provide the month and year a diagnosis was made. This usually coincides with a biopsy date if one was performed.
12. **Type of Leprosy:** Classify the diagnosis based on one of the ICD-9-CM diagnosis codes.
    030.0 Lepromatous Leprosy *(macular, diffuse, infiltrated, nodular, neuritic – includes Ridley-Jopling [RJ], Lepromatous [LL] and Borderline lepromatous [BL])*: A form marked by erythematous macules, generalized papular and nodular lesions, and variously by upper respiratory infiltration, nodules on conjunctiva or sclera, and motor loss.
    030.1 Tuberculoid Leprosy *(macular, maculoanesthetic, major, minor, neuritic – includes RJTuberculoid [TT] and Borderline tuberculoid [BT])*: A form marked by usually one lesion with well-defined margins with scaly surface and local tender cutaneous or peripheral nerves.
    030.2 Indeterminate *(uncharacteristic, macular, neuritic)*: A form marked by one or more macular lesions, which may have slight erythema.
    030.3 Borderline *(dimorphous, infiltrated, neuritic – includes RJ Borderline [BB] or true mid disease only)*: A form marked by early nerve involvement and lesions of varying stages.
    030.8 Other Specified Leprosy: Use this code when the diagnosis is specified as a "leprosy" but is not listed above *(030.0-030.3)*.
    030.9 Leprosy, Unspecified: Use this code when the diagnosis is identified as a "leprosy" but is not specified as to type.
13. Diagnosis of Disease: Enter INITIAL biopsy and skin smear dates and results.
14. **Residence *(Pre-diagnosis)*:** List all cities, counties, and states in the U.S. and all foreign countries a patient resided in BEFORE leprosy was diagnosed. This information is used to map all places where U.S. leprosy cases have resided.
15. Disability: Indicate any sensory abnormalities or deformities of the hands and feet or lagophthalmos of the eyes.
16. Current Household Contacts: Self-explanatory.
17. Current Treatment for Leprosy: Indicate all drugs used for initial treatment.
18. **Name and Address of Physician or Investigator:** Self-explanatory.

HANSEN'S DISEASE *(LEPROSY)* SURVEILLANCE FORM

NATIONAL HANSEN'S DISEASE PROGRAMS
1770 PHYSICIANS PARK DRIVE
BATON ROUGE, LA 70816
1-800-642-2477

1 Reporting State ☐☐

2 Date of Report Mo. ☐☐ Day ☐☐ Yr. ☐☐

3 Social Security Number _____/_____/_____

4 Patient Name: *(Last)* *(First)* *(Middle)*

5 Present Address: Street _____ City _____

County _____ State _____ Zip _____

6 Place of Birth:
State _____ County _____
Country _____

7 Date of Birth: Mo. ☐☐ Day ☐☐ Yr. ☐☐

Sex: ☐ Male ☐ Female

8 Race/Ethnicity: ☐ White, Not Hispanic ☐ White, Hispanic ☐ American Indian, Alaska Native ☐ Indian, Middle Easterner ☐ Black, Not Hispanic ☐ Black, Hispanic ☐ Asian, Pacific Islander ☐ Not Specified

9 Date Entered U.S. Mo. ☐☐ Yr. ☐☐

10 Date of Onset of Symptoms: Mo. ☐☐ Yr. ☐☐

11 Date Leprosy First Diagnosed: Mo. ☐☐ Yr. ☐☐

12 Type of Leprosy: *(ICD – 9- CM Code)*
☐ Lepromatous *(030.0 – LL, BL)* ☐ Indeterminate *(030.2 - IN)* ☐ Other Specified Leprosy *(030.8)*
☐ Tuberculoid *(030.1 – TT, BT)* ☐ Borderline *(030.3 - BB)* ☐ Leprosy, Unspecified *(030.9)*

13 Diagnosis of Disease:
Was Biopsy Performed? ☐ Yes ☐ No
Date _____/_____/_____
Result _____
Skin Smear ☐ Yes ☐ No
Date _____/_____/_____
BI: Positive _____ Negative _____

15 Disability:

	Hands Yes	Hands No	Feet Yes	Feet No	Eye
Sensory Loss	☐	☐	☐	☐	Lagophthalmos?
Deformity	☐	☐	☐	☐	Yes ☐ No ☐

14 List all places in the U.S.A. and all foreign countries a PATIENT resided *(Including Military Service)* BEFORE leprosy was diagnosed.

TOWN	COUNTY	STATE	COUNTRY	INCLUSIVE DATES From Mo./Yr.	INCLUSIVE DATES To Mo./Yr.

16 Current Household Contacts
Name/Relationship
1 _____
2 _____
3 _____
4 _____
5 _____

17 Current Treatment for Leprosy: *(check all that apply)*
☐ Dapsone
☐ Rifampin
☐ Clofazimine
☐ Other *(list)* _____

18 Name and Address of Physician: _____

Investigator:

This form may be FAXED to NHDP at (225) 756-3706

ATTACHMENT C

Health Resources and Services Administration
Contractor Past Performance Evaluation

---

1. FINAL REPORT _____ INTERIM REPORT _____ *(Check one)*

2. REPORTING PERIOD: *(From)* *(To)*

3. CONTRACTING OFFICER:

4. CONTRACT NUMBER:

5. CONTRACTOR NAME:
DEPARTMENT/ COMPONENT:
ADDRESS:
CITY: STATE: ZIP CODE:

6. CONTRACT AWARD DATE:
CONTRACT EXPIRATION DATE:

7. CONTRACT VALUE : $

8. DESCRIPTION OF REQUIREMENT *(Title)* :

---

9. RATINGS

Circle the number that corresponds to the rating for each category *(see attached Rating Guidelines)*, and provide comments to support the rating.

QUALITY OF PRODUCT OR SERVICE Rating 0 1 2 3 4 5
Comments:

COST CONTROL[1] Rating 0 1 2 3 4 5
Comments:

[1] Not applicable to fixed-price type contracts

Health Resources and Services Administration
Contractor Past Performance Evaluation

TIMELINESS OF PERFORMANCE Rating 0 1 2 3 4 5
Comments:

BUSINESS RELATIONS Rating 0 1 2 3 4 5
Comments:

10. SUBCONTRACTS

Are subcontracts involved? Yes No *(Circle one)*
Comments: [Briefly summarize the quality of performance of major subcontractors. This information serves two purposes: (1) it provides some insight into the contractor's effectiveness in managing its subcontractors; and (2) it provides information that may be useful for future procurements when evaluating the past performance of offerors that have only performed as subcontractors.]

11. KEY PERSONNEL

PROJECT MANAGER/PRINCIPAL INVESTIGATOR *(name)* :
Comments:

KEY PERSON *(name)* :
Comments:

KEY PERSON *(name)* :
Comments:

12. CUSTOMER SATISFACTION

Is/was the contractor committed to customer satisfaction?
Yes No *(Circle one)*

Would you recommend selection of this firm again?
Yes No *(Circle one)*

13. PROJECT OFFICER (name) :
SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

14. CONTRACTING OFFICER CONCURRENCE: *(Initial)* _____
Date:

15. CONTRACTOR'S REVIEW:
Were comments or additional information provided?
Yes No *(Circle one)*

If yes, they are:

On file in:

_____ _____
(Location) *(Phone)*
Attached: _____ *(Check if attached)*

CONTRACTOR'S REPRESENTATIVE: *(name)*

SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

---

16. AGENCY REVIEW:

Were contractor comments reviewed at a level above the contracting officer?
Yes No *(Circle one)*

If yes, Agency Decision is:
On file in:

_____ _____
(Location) *(Phone)*
Attached: _____ *(Check if attached)*

---

17. SUMMARY RATINGS:

QUALITY: _____ COST CONTROL: _____

TIMELINESS OF
PERFORMANCE: _____ BUSINESS RELATIONS: _____

---

18. CONTRACTING OFFICER *(name)* :
SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

ATTACHMENT D – BILLING INSTRUCTIONS

INVOICE INSTRUCTIONS FOR FIXED-PRICE CONTRACTS

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form 1035, Public Voucher for Purchases and Services Other Than Personal--Continuation Sheet, or the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies As indicated in the Invoice Submission clause in the contract (Section G).

Frequency Invoices submitted in accordance with the payment clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer. Invoices may be submitted in accordance with the contract payment schedule but no more frequently then monthly. The Government will consider payments made against any of these invoices as Partial Payments.

Preparation and Itemization of the Invoice The invoice shall be prepared in ink or typewriter as follows:

(a) Paying office and address

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) Description of goods or services, quantity, unit price (where appropriate), and total amount.

Currency All HRSA contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency

fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.